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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Legislation and Regulation Committee

Greg Lippe, Chair, Public Member
Ramón Castellblanch, Public Member
Randy Kajioka, Professional Member
Amy Gutierrez, Professional Member
Tappan Zee, Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee has not met in the past quarter.

PART II REGULATIONS

a. Adopted Regulations – Undergoing Review by the Administration

ATTACHMENT 1

Proposal to Amend Title 16, California Code of Regulations Section 1735.1, 1735.2, 1735.3, and 1751.2 Related to Compounding Drug Products

On July 17, 2012, the board authorized the Executive Officer to adopt the proposed regulations. Staff has compiled the rulemaking file and has submitted it to the Department for review. When approved, the file will need to be approved by the State and Consumer Services Agency before it can be transmitted to the Office of Administrative Law for final review.

This proposal was noticed for public comment on March 9, 2012. The 45-day comment period concluded on April 23, 2012, and the Board conducted a Regulation Hearing on May 1, 2012. On May 1, the board modified the language at Section 1735.3(a)(6) to incorporate by reference USP 797 related to "Redispensed CSPs"; and also to amend Section 1751.2(d) modifying the text of the special label used for cytotoxic agents. A Notice of Modified Text was issued on July 5, and the 15-day notice period concluded on July 20, 2012.

At the board meeting held July 17, 2012, the board directed that the Executive Officer adopt the regulations and compile the final rulemaking file. Staff will continue to advise the committee and the board of the status of this rulemaking that is undergoing final review.

A copy of the Adopted Text is provided in **Attachment 1**.

b. Discussion and Possible Action – Board Approved Regulations Previously Noticed

ATTACHMENT 2

Proposal to Amend Title 16, Section 1746 – Emergency Contraception Protocol

Staff Recommendation: At this meeting, staff is requesting that the board consider the modified text approved by the Medical Board of California (MBC) at its meeting held July 20, 2012. This modified text is provided in **Attachment 2**.

If approved, the board may wish to direct staff to take all steps necessary to complete the rulemaking process, including issuing the modified text for a 15-day comment period. If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt Section 1746 of the proposed regulations as noticed in the modified text notice.

Recent Updates

The Board of Pharmacy approved modified text for the Emergency Contraception Protocol at its May 2012 Board Meeting. That modified language required the concurrence of the Medical Board (MBC) before it could be released for a 15-day public comment period.

After the May 2012 Board of Pharmacy meeting, staff learned of the FDA's approval of a generic one-dose EC regimen and sought the expertise of Dr. Kathleen Hill-Besinque, the women's health specialist designated by the California Pharmacists Association. Dr. Hill-Besinque advised that including the new one-dose regimen would keep the protocol up to date. She also encouraged the board to clarify the dosing instructions in the Table of Dedicated Emergency Contraception. As a result, Board staff drafted additional modified text that included the new one-dose regimen and that also clarified the dosing instruction – staff provided both the language approved by the Board of Pharmacy (in May 2012) as well as the newly drafted modifications to the MBC for consideration.

When the MBC met on July 20, 2012, it considered and approved the modified text that included the newly approved generic one-dose regimen and that clarified dosing instructions. In addition, the MBC made modifications to the language at § 1746(b)(3), striking the language related to the insertion of an IUD and further modified the subdivision to encourage patients to follow up with their physician or healthcare provider after the use of emergency contraception. It is this modified language that is before the board for consideration today.

Background

Business and Professions Code Section 4052.3 authorizes a pharmacist to initiate emergency contraception therapy in accordance with either (1) standardized procedures

or protocols developed by the pharmacist and an authorized prescriber, as specified; and (2) standardized procedures or protocols developed and approved by both the Medical Board of California and the Board of Pharmacy, as specified.

The current state protocol was developed by the Medical Board in 2004 and was adopted by the Board of Pharmacy that same year. Title 16 CCR § 1746 became operative on December 2, 2004. Since that time, there have been changes in the availability of emergency contraception medicine, the manufacturers who produce the medication. The protocol also has a typographical error that requires correction (mcg instead of mg).

The board voted in October 2011 to initiate this rulemaking. The Notice of proposed text was issued on January 6, 2012, and the 45-day public comment period concluded on February 20, 2012. The board received one comment during that period, which was rejected by both the Board of Pharmacy and the Medical Board of California.

Following the adoption of a new emergency contraception protocol, the board will then need to update its patient information fact sheet. This fact sheet is required by Section 4052.3(e) of the Business and Professions Code and is provided to the patient by the pharmacist using the protocol to dispense emergency contraception. The update of a fact sheet would be vetted through the board's Communication and Public Education Committee.

c. Board Approved Regulations – Currently Noticed

1. Combined Rulemaking related to e-Pedigree: Proposal to Add Section 1747 – Requirement to Specify a Unique Identification Number for Prescription Medication, and to Add Section 1747.1 – Grandfathering

ATTACHMENT 3

On September 21, 2012, the board issued a Notice of a proposed rulemaking related to e-Pedigree. Specifically, the board proposed to add section 1747 to specify the requirements of a unique identification number for prescription medication, and to add section 1747.1 related to declarations that are to be filed with the board regarding existing drug stock (grandfathering) and suppliers' readiness to comply with statutory e-Pedigree provisions. The board is accepting written comments to the proposal until 5:00 p.m. on November 5, 2012. Comments received will be brought to the board at the January 2013 Board Meeting for consideration and possible action.

A copy of the board's proposal is provided in **Attachment 3.**

2. Combined Rulemaking: Proposal to Amend Section 1745 – Partial Fill of Schedule II Controlled Substance Prescription; Add Section 1762 – Unprofessional Conduct; and Add Section 1769 – Criteria for Rehabilitation

ATTACHMENT 4

The Board's notice of proposed rulemaking will be published in the *California Regulatory Notice Register* on October 19, 2012. The 45-day public comment period will conclude on December 3, and the comments will be brought back to the board for consideration at the January 2013 Board Meeting. A copy of the board's proposal is provided in **Attachment 4.**

Background

Proposal to add Section 1762 – Unprofessional Conduct: Defined

In February 2011, the board moved to initiate a rulemaking to add Section 1762 to Title 16 California Code of Regulations to implement components of the Department of Consumer Affairs' Consumer Protection Enforcement Initiative (CPEI) relative to unprofessional conduct. The provisions would specify that unprofessional conduct include acts such as gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender.

Proposal to amend Section 1745 – Partial Fill of Schedule II Controlled Substance

Current regulation requires that when a pharmacist partially fills a prescription for a Schedule II controlled substance that specified information be recorded in a readily retrievable form and also on the original prescription document. The board approved draft language to allow a pharmacist to record specified information in a readily retrievable form ***or*** on the original prescription document.

Proposal to amend Section 1769 – Criteria for Rehabilitation

To implement components of the DCA's CPEI, the board directed that staff initiate a rulemaking that would authorize the board to request an applicant for licensure to undergo an examination, as specified, to determine if the applicant is safe to practice. The board further specified that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days, and that within 60 days of the evaluation, the report be received by the board.

d. Board Approved Regulations – Awaiting Formal Public Notice

ATTACHMENT 5

Board staff is preparing a combined rulemaking to Notice the following board-approved proposals. A copy of the language approved for notice is provided in **Attachment 5**.

Amend Section 1732.2 – Board Accredited Continuing Education
Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas
Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education
Add Section 1751.9 – Standards for Agencies that Accredit Sterile Injectable Compounding Pharmacies

Background

Proposal to Amend Section 1732.2 – Board Accredited Continuing Education
In January 2012, the board withdrew a pending regulation to Section 1732.2 which, at that time, was pending final review at the Office of Administrative Law. The matter was referred back to the Licensing Committee for discussion. In May 2012, the board considered language recommended by the Licensing Committee and voted to initiate a rulemaking.

Proposal to Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas
In early 2012, the board considered requirements to require continuing education in specific content areas, and referred the matter to the Licensing Committee. At the May 2012 Board Meeting, the board considered and approved for notice proposed text to require six of the 30 units required of continuing education for a pharmacist renewal be in specified content areas.

Proposal to Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education
At the May 2012 Board Meeting, the board considered a request from the California Pharmacists Association to modify Section 1732.05 to reflect the restructuring of the Pharmacy Foundation of California and its transference of duties related to the provision of continuing education to the California Pharmacists Association. At that meeting the board voted to amend Section 1732.05 and to initiate a formal rulemaking to update the reference at Section 1732.05(a)(2).

Proposal to Add Section 1751.9 – Standards for Agencies that Accredit Sterile Injectable Compounding Pharmacies
At the May 2012 Board Meeting the board considered and approved a recommendation from the Licensing Committee to adopt requirements to specify standards for agencies that accredit licensed sterile injectable compounding pharmacies, and voted to initiate a rulemaking to add Section 1751.9.

e. Under Development

The following proposals were previously considered by the Legislation and Regulation Committee but have been referred to other committees or subcommittees of the board.

1. Proposal to Amend Section 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers). [Referred to a subcommittee.]

   Background
   Section 1780 of the California Code of Regulations sets minimum standards for drug wholesalers. This regulation currently references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. USP Standards are updated and published annually. Section 1780(b) requires amendment to reflect the 2005 version of the USP Standards and to hold wholesalers accountable to the latest standards, if determined appropriate.

   Because of stated concerns about whether referencing the 2005 USP Standards would be an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

   The board established a subcommittee for this purpose but, as a result of board vacancies, the subcommittee has not held any meetings and no action has been taken with respect to this regulation change. At the May 2012 Board Meeting, Board President Weisser encouraged the board to begin work in this area soon.

2. Proposal to Amend Section 17985 – Self-Assessment of a Veterinary Food-Animal Drug Retailer [referred to Licensing Committee]

   Background
   The requirements of § 1785 establish a self-assessment form for veterinary food-animal drug retailers and requires a designated representative-in-charge to complete this form to ensure compliance with pharmacy law. Self-assessment forms also aid licensees in complying with legal requirements of their operations and, therefore, increase public safety as a result of this compliance.

   In 2007 the Enforcement Committee and the Board approved draft amendments to the regulation and related self-assessment form; subsequently, the licensing committee was advised of potential problems with the licensing requirements for designated representatives working at these facilities.

   The Licensing Committee has not yet initiated a program review of the Veterinary Food-Animal Drug Retailer program. At such time that the committee completes a review, draft language will be brought back to the board for reconsideration.

f. Discussion and Possible Action to Delegate to the Executive Officer the Authority to Adopt "Changes Without Regulatory Effect" (1 CCR § Section 100 Changes)

ATTACHMENT 6

The Administrative Procedure Act specifies the requirements and process to establish a regulation. (See Chapter 3.5, commencing with section 11340, Part 1, Division 3, Title 2 of the Government Code.) The board must authorize or delegate the authorization of the adoption of a regulation related to Pharmacy Law.

In addition to the 'regular' rulemaking process, Title 1 of the California Code of Regulations section 100 specifies the requirements for regulatory changes that are "without regulatory effect." These types of "Section 100" changes would include (1) grammatical corrections, (2) updating, reordering, renumbering or re-locating the laws or regulations listed on the self-assessment forms, and (3) updating the authority and reference citations for regulations when the number of the cited statutes or regulations changes, and other types of changes that do not materially alter any requirement, right, responsibility, condition, or other regulatory element of a regulation. A copy of Title 1 CCR § 100 is provided in **Attachment 6**.

The last time the board completed a Section 100 rulemaking was in 2009, when the board updated its self-assessment forms. The board will soon be updating its self-assessment forms to reflect reference changes as a result of statutory changes made in the past year. Because updating a 'reference' would meet the requirements of 1 CCR § 100, and if the Executive Officer were delegated the authority to adopt such a rulemaking, the Executive Officer could file such a regulation change without requiring an additional motion by the board.

A Section 100 rulemaking process is significantly shorter than a "regular" rulemaking. Title 1 CCR § 100 provides that upon the filing of a Section 100 regulation change, OAL will make a determination within 30 days. A "regular" rulemaking lasts about a year. If a Section 100 change is filed with OAL, and it does not meet the requirements of Section 100, OAL will notify the agency and return the file.

Staff is recommending that for a specified period of time (in this case, November 1, 2012 through December 2013), the board delegate to the Executive Officer its authority adopt ***only*** those regulations that are deemed "without regulatory effect" that meet the requirements of Section 100 of Title 1 of the California Code of Regulations.

Staff Recommendation: *For the period November 1, 2012 through December 31, 2013, the board delegate to the Executive Officer the authority to adopt regulation changes that are deemed to be "without regulatory effect" in accordance with Section 100 of Title 1 of the California Code of Regulations. Upon the adoption of any "Section 100" regulatory changes, the Executive Officer shall report to the board at its next regularly scheduled Board Meeting any regulations authorized by this motion.*

e. Discussion and Possible Action to Initiate a Rulemaking to Amend California Code of Regulations, Title 16, Section 1760 – Disciplinary Guidelines, and to Add a New Section Regarding Implementation of Uniform Standards for Substance Abusing Licensees

ATTACHMENT 7

Relevant Sections

California Code of Regulations Section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action.

Business and Professions Code Section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs. The committee was charged with formulating uniform and specific standards in several areas for dealing with substance-abusing licensees.

Chapter 9, Division 2, Chapter 19 (business and professions code sections 4300-4315) defines disciplinary proceeding for the board as well as the grounds for taking such discipline.

Background

Last year the board directed staff to a restructuring and updating of its Disciplinary Guidelines last year. Subsequent to this, in April 2011, the SACC finalized the uniform standards required in B&PC section 315. At that time it was understood that the standards needed to be incorporated into the board's disciplinary guidelines to facilitate implementation.

During the July 2011 Board meeting, staff was directed to incorporate the uniform standards into the disciplinary guidelines for consideration by the board at a future meeting. During the September 2011 Board Meeting, the board voted to pursue a regulation change to disciplinary guidelines which were noticed in October 2011 and later modified during the January 2012 board meeting.

More recently, during the May 2012 Board Meeting, the board was advised of a recent advice provided to the department from the Government Law Section of the Attorney General's Office as well as a legal opinion from the Legislative Counsel Bureau. Based on these opinions, the department sent memorandum clarifying that the board has no discretion on how to implement the standards. The board was advised of two options – proceeding as is or rescinding the current regulation. Two areas where the board has discretion were identified including: (1) whether the Uniform Standards should be placed in a regulation separate from the Disciplinary Guidelines; and (2) if the regulation should include a definition of (or criteria by which to determine) what constitutes a "substance-abusing licensee." Based on this information the board voted to rescind the current rulemaking file and requested that counsel craft language to facilitate implementation of the standards as well as language to define "substance-abusing licensee."

Recent Update

Staff is bringing to the board drafted Disciplinary Guidelines that reorganize the format and add several new terms. A copy of these guidelines is provided in **Attachment 7**.

Still under development is the method by which the board will incorporate the SB 1441 Standards into the guidelines. A discussion is planned for the board meeting to discuss options. By practice the board has already implemented many of these standards for pharmacy technician. Pharmacists and interns are already subject to these standards via the PRP program. Once all outstanding issues are resolved, the standards will be formally adopted.

In the interim, board staff is requesting the board approve the proposed changes to the existing disciplinary guidelines and authorize staff to move forward with the regulation process. These changes will address challenges staff currently face with monitoring licensees on probation with the board as well as incorporate much of the uniform standard language that is incumbent upon a licensee to comply.

Provided below is a list of each of the proposed changes to the guidelines.

Changes resulting from reorganization of the guidelines

- Consolidation of all of the individual license types.
- Removal of all legal citations under each separate category of violations
- Improved definitions and inclusion of sample violations within each category of violation.

Individual Licensees

New terms of probation
- Suspension

Changes to existing terms of probation
- Cooperate with Board Staff
- Restrictions on Supervision and Oversight of Licensed Facilities
- Reimbursement of Board Costs
- Certification Prior to Resuming Work (Pharmacy Technician Only)
- Notification of Departure
- License Practice Requirements – Tolling
- Restricted Practice
- Pharmacist Exam (Pharmacists Only)
- Psychotherapy
- Medical Evaluation
- Pharmacists Recovery Program (Pharmacists and Pharmacist Interns Only)
- Abstain from Drugs and Alcohol
- Prescription Coordination and Monitoring of Prescription Use
- Community Service Program
- Supervised Practice
- Surrender of DEA Permit (Pharmacists and Pharmacist Interns Only)

- Ethics Course

Changes to incorporate SB 1441 Uniform Standards

- Reporting of Employment and Notice to Employers (Uniform Standard 3)
- Clinical Diagnostic Evaluation (Uniform Standard 1 and 2)
- Drug and Alcohol Testing (Uniform Standard 4)
- Facilitated Group Recovery and/or Support Meetings (Uniform Standard 5)
- Work Site Monitor (Uniform Standard 7)

Premises Licensees

New terms of probation

- Definition: Respondent
- Sale or Discontinuance of Business
- Premises Open for Business
- Suspension

Changes to existing terms of probation

- Cooperate with Board Staff
- Reimbursement of Board Costs
- Status of License
- Posted Notice of Probation
- Report of Controlled Substances
- Posted Notice of Suspension

Order of Adoption
Board of Pharmacy
California Code of Regulations

Amend Section 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.1. Compounding Definitions.

(a) "Equipment" means items that must be calibrated, maintained or periodically certified.

~~(a)~~ (b) "Integrity" means retention of potency until the expiration date noted on the label.

~~(b)~~ (c) "Potency" means active ingredient strength within +/- 10% of the labeled amount.

~~(c)~~ (d) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

~~(d)~~ (e) "Strength" means amount of active ingredient per unit of a compounded drug product.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

Amend Section 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of

patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

~~(2)~~ (4) Inactive ingredients to be used.

~~(3)~~ (5) Process and/or procedure used to prepare the drug.

~~(4)~~ (6) Quality reviews required at each step in preparation of the drug.

~~(5)~~ (7) Post-compounding process or procedures required, if any.

~~(6) Expiration dating requirements.~~

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. ~~01/11~~ 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend Section 1735.3 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.3. Records of Compounded Drug Products.

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within ~~twenty-four~~ seventy-two (72) hours and stored in accordance with United States Pharmacopeia Standards for "REDISPENSED CSPs" in Chapter 797 (35th Revision, Effective May 1, 2012), which is hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

~~(7) The equipment used in compounding the drug product.~~

~~(8)~~ (7) A pharmacy assigned reference or lot number for the compounded drug product.

~~(9)~~ (8) The expiration date of the final compounded drug product.

~~(10)~~ (9) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Note: Authority cited: Sections 4005, 4127 and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend Section 1751.2 of Article 7 of Division 17 of Title 16 to read as follows:

§ 1751.2. Sterile Injectable Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

(a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.

(b) Name and concentrations of ingredients contained in the sterile injectable product.

(c) Instructions for storage and handling.

(d) All cytotoxic agents shall bear a special label which states "Chemotherapy - Dispose of Properly." or "Cytotoxic ~~Product~~ – Dispose of Properly."

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Virginia Herold
Executive Officer
Board of Pharmacy

This version was approved by Med Bd 7/20/12

Board of Pharmacy
Modified Language

To Amend § 1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section ~~4052(a)(8)~~ 4052.3.(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

~~(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.~~

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication ~~within required limits~~ and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and ~~state~~ communicate the following:

> Are you allergic to any medications?
>
> Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) ~~of~~ after unprotected intercourse. ~~EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.~~
>
> EC use will not interfere with an established or implanted pregnancy.

Changes to the originally proposed language are shown as follows:
Deleted text is shown by double strike-through, thus: ~~deleted language~~.
New or added text is shown by double underline, thus: added language.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. For ***other*** ~~***Other***~~ options for EC ~~***include consultation***~~ ***consult*** with your **health care provider** ~~**physician regarding insertion of an IUD**~~.

Please follow up with your health care provider after the use of EC.

(4) The pharmacist shall provide ~~the~~ a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in ~~the~~ this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

Changes to the originally proposed language are shown as follows:
Deleted text is shown by double strike-through, thus: ~~deleted language~~.
New or added text is shown by double underline, thus: added language.

(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Dedicated Emergency Contraception

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynétics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	**Manufacturer**	**Tablets per Dose (two doses 12 hours apart*)**	**Ethinyl Estradiol per Dose (mg)**	**Levonorgestrel per Dose (mg)****
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in eachdoes is twice the amount of levonorgestrel

Changes to the originally proposed language are shown as follows:
Deleted text is shown by double strike-through, thus: ~~deleted language~~.
New or added text is shown by double underline, thus: added language.

(11) Medications Used for Emergency Contraception

Dedicated Approved Products for Emergency Contraception

Brand	Dose	Ethinyl Estradiol per dose (mcg)	
One Tablet ~~Dose~~ Regimen			
Plan B™ One-Step	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
Levonorgestrel	1 tablet	0	1.5mg levonorgestrel
Two Tablet ~~Dose~~ Regimens			
Next Choice™	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later ~~1 tablet per dose~~	0	*Each tablet is 0.75 mg* ~~1.5mg~~ levonorgestrel
Levonorgestrel	2 tablets at once (1.5mg total dose) or 1 tablet (0.75mg) followed by 1 tablet (0.75mg) 12 hours later	0	*Each tablet is 0.75 mg levonorgestrel*

Oral Contraceptive Pills

Brand	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)*
Alesse	5 pink tablets	100	0.50
Aviane	5 orange tablets	100	0.50
Levlen	4 light-orange tablets	120	0.60
Levlite	5 pink tablets	100	0.50
Levora	4 white tablets	120	0.60
Lo/Ovral	4 white tablets	120	0.50
Low-Ogestrel	4 white tablets	120	0.60
Nordette	4 light-orange tablets	120	0.60
Oqestrel	2 white tablets	100	0.50
Ovral	2 white tablets	100	0.50
Tri-Levlen	4 yellow tablets	100	0.50
Triphasil	4 yellow tablets	120	0.50

Changes to the originally proposed language are shown as follows:
Deleted text is shown by double strike-through, thus: ~~deleted language~~.
New or added text is shown by double underline, thus: added language.

Trivora	4 pink tablets	120	0.50
Ovrette	20 yellow tablets	0	0.75

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Anti-Nausea Treatment Options For Use With Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ~~ECP~~ EC dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

Changes to the originally proposed language are shown as follows:
Deleted text is shown by double strike-through, thus: ~~deleted language~~.
New or added text is shown by double underline, thus: added language.

Title 16. Board of Pharmacy
Proposed Language

Proposal to Add a New Article 5.5 and Article Title, and Add Sections 1747 and 1747.1 and Section Titles to Article 5.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 5.5. Pedigree Requirements.

1747. Unique Identification Number.

For the purposes of Section 4034 of the Business and Professions Code, the "unique identification number" that is to be established and applied to the smallest package or immediate container by the manufacturer or repackager shall conform to requirements for Standardized Numerical Identifiers (SNIs) set forth in a March 2010 publication by the U.S. Food and Drug Administration (FDA) titled "Guidance for Industry, Standards for Securing the Drug Supply Chain – Standardized Numerical Identification for Prescription Drug Packages," (FDA'S Guidance Document), hereby incorporated by reference. As stated therein, an SNI consists of a serialized National Drug Code (NDC) product identifier combined with a unique numeric or alphanumeric serial number of no more than twenty (20) digits or characters. For dangerous drugs for which no NDC product identifier is assigned or is in use, an equivalent serialized product identifier may be used in place of the NDC consistent with the FDA's Guidance Document. This number shall be combined with a unique numeric or alphanumeric serial number that is not more than 20 digits or characters in length to establish the unique identification number.

This regulation shall become operative on January 1, 2015.

Note: Authority cited: Sections 4005, 4034, and 4163.2, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

1747.1. Specification of Pedigreed Dangerous Drugs; Specification of Existing Stock

(a)(1) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall submit to the board, by December 1, 2014, but no later than December 31, 2014, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of dangerous drugs by name and product package (SKU) type representing at least fifty (50) percent of the manufacturer's total that are ready for initial implementation of the serialized electronic pedigree requirements as of January 1, 2015;

(B) A statement identifying which one of the following methods was used to measure the percentage of drugs ready to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the percentage figure of dangerous drugs ready for serialized pedigree requirements;

(D) A list and quantity of dangerous drugs by name and product package (SKU) type that are in the remaining percentage not yet ready to be serialized or subject to pedigree requirements; and,

(E) a statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(2) To comply with Business and Professions Code section 4163.5, each manufacturer of a dangerous drug distributed in California shall also submit to the board, by December 1, 2015, but no later than December 31, 2015, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, containing the following:

(A) A list and quantity of its remaining dangerous drugs by name and product package (SKU) type that are ready for implementation of serialized electronic pedigree requirements as of January 1, 2016.

(B) A statement identifying which one of the following methods was used to measure the final percentage of drugs to be serialized: (i) unit volume, (ii) product package (SKU) type, or (iii) drug product family;

(C) A statement describing the calculation(s) used to arrive at the final percentage figure; and,

(D) A statement specifying the technology employed to meet the pedigree requirements, including but not limited to any platform(s), vendor(s), hardware, software, and communication technologies deployed.

(3) Any failure to submit to the board a declaration compliant with subdivision (a)(1) by December 31, 2014, any failure to submit to the board a declaration compliant with subdivision (a)(2) by December 31, 2015, or any failure to re-submit either declaration to the board in fully compliant form within ten (10) days after notice of deficiency by the board, shall constitute a violation of the Pharmacy Law.

(b) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any manufacturer, wholesaler or repackager seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2016, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the manufacturer, wholesaler or repackager, containing the following:

(1) a list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the manufacturer, wholesaler or repackager that were acquired prior to July 1, 2016;

(2) a statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(c) For the purposes of Business and Professions Code sections 4163.2 and 4163.4, any pharmacy or pharmacy warehouse seeking to designate dangerous drugs it possesses, owns, or controls that are not subject to the serialized electronic pedigree requirements, shall submit to the Board, by no later than August 1, 2017, a declaration signed under penalty of perjury by an owner, officer, or employee with authority to bind the pharmacy or pharmacy warehouse, containing the following:

(1) A list and quantity of dangerous drugs by name, product package (SKU) type and National Drug Code (NDC) product identifier in the possession, ownership, or control of the pharmacy or pharmacy warehouse that were acquired prior to July 1, 2017;

(2) A statement that specifies the means and source of acquisition; and,

(3) a statement that specifies the anticipated means of any subsequent distribution or disposition.

(d) The Board or its designee shall have sole discretion to determine whether any of the declarations submitted pursuant to this Section are compliant, and to reject and require re-submission of any non-compliant declaration(s) until determined to be fully compliant.

Note: Authority cited: Sections 4005, 4034, 4163, 4163.2 and 4163.5, Business and Professions Code. Reference: Sections 4034, 4034.1, 4163, 4163.1, 4163.2, 4163.4, 4163.5, Business and Professions Code.

Title 16. Board of Pharmacy
Proposed Language

To Amend Section 1745 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1745. Partial Filling of Schedule II Prescriptions.
(a) A prescription for a Schedule II controlled substance (as defined in Health and Safety Code section 11055) may be partially filled, as defined in paragraph (b), if:

(1) The prescription is for an inpatient of a skilled nursing facility as defined in Health and Safety Code section 1250; or

(2) The prescription is for a terminally ill patient. "Terminally ill" as used herein means a patient for whom a licensed physician and surgeon has made and documented a diagnosis of illness or disease that will result in death.

(b) A "partially filled" prescription is a prescription from which only a portion of the amount for which the prescription is written is filled at any one time; provided that regardless of how many times the prescription is partially filled, the total amount dispensed shall not exceed that written on the face of the prescription.

(c) When partially filling a prescription pursuant to subsection (a), all of the following conditions must be met:

(1) The prescription must be tendered and at least partially filled within 60 days following the date of issue;

(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

(3) No portion of the prescription is dispensed more than 60 days from the date of issuance of the prescription; and

(d) A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if the pharmacist is unable to supply the full quantity ordered by the prescriber. The pharmacist shall make a notation of the quantity supplied on the face of the written prescription. The remaining portion of the prescription may be filled within 72 hours of the first partial filling. If

the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the prescriber. The pharmacist may not supply the drug after 72 hour period has expired without a new prescription.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4301, Business and Professions Code; and Sections 11055, 11153, 11154, 11166, 11200, Health and Safety Code.

To Add Section 1762 to Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

To Amend Section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1769. Criteria for Rehabilitation.

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

(1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.

(2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.

(3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).

(4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

(1) Nature and severity of the act(s) or offense(s).

(2) Total criminal record.

(3) The time that has elapsed since commission of the act(s) or offense(s).

(4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.

(5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4200 and 4400, Business and Professions Code.

Title 16. Board of Pharmacy
Proposed Language

To Amend § 1732.05 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.05. Accreditation Agencies for Continuing Education.

(a) The following organizations are approved accreditation agencies:

(1) The Accreditation Council for Pharmacy Education.

(2) The ~~Pharmacy Foundation of California~~ California Pharmacists Association.

(b) Accreditation agencies shall:

(1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.

(2) Maintain a list of the name and address of the person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.

(5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.

(6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board.

(7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

To Amend § 1732.2 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of continuing education for conducting a review of exam test questions. A subcommittee member shall not receive continuing education hours pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.

(d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded six hours of continuing education per renewal period. The board shall designate on its public agenda which day shall be eligible for continuing education credit. A pharmacist or pharmacy technician requesting continuing education pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded two hours of continuing education per renewal period. A pharmacist or pharmacy technician requesting continuing education hours pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

(f) An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

To Amend § 1732.5 in Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:

1. Emergency/Disaster Response
2. Patient Consultation
3. Maintaining Control of a Pharmacy's Drug Inventory
4. Ethics
5. Substance Abuse

Pharmacists renewing their licenses which expire on or after July 1, 2015, shall be subject to the requirements of this subdivision.

~~(b)~~ (c) All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

To Add § 1751.9 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1751.9. Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

(a) An agency seeking to become an approved accrediting agency for pharmacies or nonresident pharmacies that compound sterile injectable drug products pursuant to Business and Professions Code sections 4127.1 or 4127.2 shall submit evidence satisfactory to the board as described in subdivision (b) that:

(1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least annually. Site inspections shall be conducted to ensure compliance with Article 4.5 (commencing with Section 1735) and Article 7 (commencing with Section 1751) of Division 17 of Title 16 of the California Code of Regulations governing the compounding of sterile injectable drug products.

(2) The standards for granting accreditation shall reflect the Pharmacy Law.

(3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation. At least one member of the survey team must be a licensed pharmacist.. All health care practitioner surveyors must maintain current, active and unrestricted licensure to practice their respective professions.

(4) The accrediting agency has sufficient personnel and resources to accredit California and non-resident pharmacies.

(5) The accrediting agency has been operating for a minimum of two years with a history of accrediting health care facilities.

(6) The accrediting agency shall provide the board access to an approved accrediting agency's report on individual pharmacies for a three-year period following issuance of the report. Upon request of the board, the agency shall provide the report within 10 business days.

(b) An agency seeking approval from the board must submit a formal written request to the board signed by an authorized representative that includes the applicant owner's name, the company name, address of record, and contact information along with the following information:

(1) A side-by-side comparison showing the agency's sterile compounding standards and describing how each standard complies with each of the requirements of this Section).

(2) A list of employees performing survey inspections that also sets forth the name, title, license number, license type, state of licensure and licensure status for each employee.

(3) A list of payers or organizations that the agency is recognized by, if applicable.

(4) A list of health care facility sites currently accredited by the agency including the name, location, license type and license number of each site.

(5) A detailed description of the process used to evaluate health care facility sites seeking accreditation or reaccreditation.

(6) Documentation of compliance with the requirements listed in the self-assessment form referenced in section 1735.2(j) of Title 16 of the California of Code of Regulations in evaluating pharmacies and non-resident pharmacies.

(7) Documentary or other evidence of a process to address non-compliance that may include any or all of the following: (a) a requirement for correction of any identified deficiencies within

a set timeframe; (b) a requirement that failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the accreditation; or, (c) a process for suspending or revoking the licensed sterile injectable drug compounding pharmacy's accreditation.

(c) The Board of Pharmacy shall take action on a completed application at a scheduled board meeting, as follows:

(1) If granted, the approval shall be valid for three years from the date of action by the board.

(2) If the approval is denied, the agency will be notified of the basis for the denial, including a description of the standards that were not met. The agency may submit additional information to the board for reconsideration of the denial within 30 days of the date of the notice of denial. The reconsideration shall be considered at a scheduled board meeting and the accrediting agency may show compliance with the standards set forth in this Section by producing new documentary evidence, providing testimony or submitting other evidence demonstrating why the approval should be granted.

(d) After approval, an approved accreditation agency shall continue to meet the standards provided in this Section and meet any conditions under which it is approved by the board. Failure to comply with the standards set forth in this section or any conditions set by the board shall be grounds for rescission of the board's approval.

(e) The accreditation agency shall, within 24 hours, report to the board any licensed sterile injectable drug compounding pharmacy issued a reprimand or any licensed sterile injectable drug compounding pharmacy whose accreditation has been suspended, revoked, or otherwise restricted by the accrediting agency.

(f) On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a report to the board listing all board-licensed pharmacies or nonresident pharmacies that are currently accredited and have been accredited during the past 12 months with a notation of the outcome of each inspection conducted by the accrediting agency.

(g) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with the Pharmacy Law. An accrediting agency shall cooperate with any board investigation or inspection conducted by the board.

(h) Three months before the end of an approval or re-approval period, an approved accrediting agency must submit a formal, written request for re-approval to the board or its designee for continued recognition as an approved accrediting agency. The re-approval request shall provide the information set forth in subdivision (b). If the re-approval application fails to demonstrate compliance with this Section, or the board has evidence that the accrediting agency has failed to meet the requirements of this section, the Board or its designee may issue and serve a notice of denial of re-approval on the accrediting agency at its address of record with the board. The denial shall set forth the factual and legal basis for the denial. Within 30 days of the date of the notice, the accrediting agency may request an appeal of the decision to deny re-approval. If no appeal is requested, the denial shall become final. If the board

receives a request for an appeal of the notice, the request for an appeal shall be considered a request for an informal hearing under the Administrative Procedure Act (commencing with Section 11445.10 of the Government Code).

(i) Recognition of an approval shall continue pending the outcome of any appeal from a notice of denial or rescission of any approval. However, if either a denial or rescission of an approval is upheld after appeal, the accrediting agency shall notify all affected pharmacies or nonresident pharmacies of the loss of the board's approval.

(j) The board may evaluate the performance of an approved accreditation agency and may rescind its approval of the accreditation agency for failure to conform with the Pharmacy Law and standards relating to sterile injectable drug compounding or any of the provisions of this section. The Board or its designee may issue and serve a notice of rescission of approval on the accrediting agency at its address of record with the board. The rescission notice shall set forth the factual and legal basis for the rescission and set forth the process for appealing the notice. Within 30 days of the date of the notice, the accrediting agency may request an appeal of the decision to rescind approval. If no appeal is requested, the denial shall become final. If the board receives a request for an appeal of the notice, the request for an appeal shall be considered a request for an informal hearing under the Administrative Procedure Act (commencing with Section 11445.10 of the Government Code).

Title 1. General Provisions
Division 1. Office of Administrative Law
Chapter 1. Review of Proposed Regulations
Article 2. Criteria Applied in the Review of Proposed Regulations

§ 100. Publication of "Changes Without Regulatory Effect."

(a) Subject to the approval of OAL as provided in subsections (c) and (d), an agency may add to, revise or delete text published in the California Code of Regulations without complying with the rulemaking procedure specified in Article 5 of the APA only if the change does not materially alter any requirement, right, responsibility, condition, prescription or other regulatory element of any California Code of Regulations provision. Subject to the approval of OAL, the Department of Social Services may add to, revise or delete text published in the department Manual of Policies and Procedures (MPP) without complying with the rulemaking procedure specified in Article 5 of the APA only if the change does not materially alter any requirement, right, responsibility, condition, prescription or other regulatory element of the MPP. The addition, revision or deletion is a "change without regulatory effect." Changes without regulatory effect include, but are not limited to:

(1) renumbering, reordering, or relocating a regulatory provision;

(2) deleting a regulatory provision for which all statutory or constitutional authority has been repealed;

(3) deleting a regulatory provision held invalid in a judgment that has become final, entered by a California court of competent jurisdiction, a United States District Court located in the State of California, the United States Court of Appeals for the Ninth Circuit, or the United States Supreme Court; however, OAL shall not approve any proposed change without regulatory effect if the change is based on a superior court decision which invalidated the regulatory provision solely on the grounds that the underlying statute was unconstitutional;

(4) revising structure, syntax, cross-reference, grammar, or punctuation;

(5) changing an "authority" or "reference" citation for a regulation; and,

(6) making a regulatory provision consistent with a changed California statute if both of the following conditions are met:

(A) the regulatory provision is inconsistent with and superseded by the changed statute, and

(B) the adopting agency has no discretion to adopt a change which differs in substance from the one chosen.

(b) In submitting a change without regulatory effect to OAL for review the agency shall:

(1) submit seven copies of the regulations with an addition shown in underline or italics and a deletion shown in strike-out; and

(2) attach to each copy a completed Form 400, with at least one Form 400 bearing an original signature; and

(3) submit a written statement explaining why the change does not materially alter any requirement, right, responsibility, condition, prescription or other regulatory element of any California Code of Regulations provision.

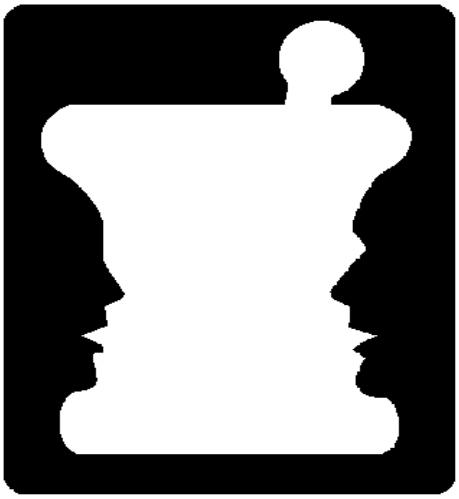
(c) OAL shall determine whether a change submitted is a change without regulatory effect within 30 working days of its receipt. OAL shall send written notification of the determination to the agency which submitted the changes.

(d) If OAL determines that the submitted change is a change without regulatory effect, OAL shall file it with the Secretary of State and have it published in the California Code of Regulations. If the change without regulatory effect is a change to the MPP, OAL shall file the change with the Secretary of State and the Department of Social Services shall publish the change in the MPP.

Note: Authority cited: Sections 11342.4 and 11349.1(c), Government Code. Reference: Sections 11342.600, 11343.8, 11344.6 and 11346, Government Code; and Article III, Section 3.5, California Constitution.

DISCIPLINARY GUIDELINES

A Manual of Disciplinary Guidelines
and Model Disciplinary Orders



BE AWARE & TAKE CARE:
Talk to your pharmacist!

California State Board of Pharmacy
Department of Consumer Affairs
(Rev. ~~10/2007~~ 12/2012)

STATE BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS

~~**William Powers**~~
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Additional copies of these disciplinary guidelines
may be downloaded from the board's website

BOARD OF PHARMACY

DISCIPLINARY GUIDELINES

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DEPARTMENT OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

DISCIPLINARY GUIDELINES
(Rev. ~~10/2007~~ 9/2012)

INTRODUCTION

The Board of Pharmacy (board) is responsible for the enforcement of statutes and regulations related to the practice of pharmacy (the Pharmacy Law) and to the regulation of controlled substances (the Uniform Controlled Substances Act). The board serves the public by:

- protecting the health, safety, and welfare of the people of California with integrity and honesty;
- advocating the highest quality of affordable pharmaceutical care;
- providing the best available information on pharmaceutical care; and
- promoting education, wellness and quality of life.

Pharmacists are patient advocates who provide pharmaceutical care and exercise clinical judgment ~~for the citizens of California~~ for their patients, enlightening them about their drug therapy through effective communicating and listening, assessing, collaborating, understanding and intervening. Enforcement officials act quickly, consistently and efficiently in the public's interest to ensure the safe, effective delivery of these services.

The board recognizes the importance of ensuring the safe and effective delivery of dangerous drugs and controlled substances for therapeutic purposes. At the same time, and given the historical and current abuse and diversion of drugs, particularly controlled substances, the board believes there should be no tolerance for licensees who traffic in drugs or who, in the absence of appropriate evidence of rehabilitation, personally abuse drugs or alcohol.

In accordance with Section 1760 of the California Code of Regulations, the board has produced this booklet for those involved in and affected by the disciplinary process: the general public, board licensees, attorneys from the Office of the Attorney General, administrative law judges from the Office of Administrative Hearings, defense attorneys, ~~board licensees~~, the courts, board staff and board members who review and vote on proposed decisions and stipulations.

These guidelines are to be followed in Board of Pharmacy disciplinary actions. Subject to judicial review, the board has the final authority over the disposition of its cases, and, to complete its work, it uses the services of the Office of the Attorney General and the Office of Administrative Hearings. The board recognizes that individual cases may necessitate a departure from these guidelines. In such cases, the mitigating or aggravating circumstances shall be detailed in any proposed decision or any transmittal memorandum accompanying a proposed stipulation, especially where Category III or IV violations are involved.

In general, the position of the board is that revocation should always be an option whenever grounds for discipline are found to exist. Board policy is that revocation is generally an appropriate order where a respondent is in default, such as when he or she fails to file a notice of defense or fails to appear at a disciplinary hearing.

Board policy is that a suspension, where imposed, should be at least 30 days for an individual and at least 14 days for a licensed premises.

The board seeks recovery of all investigative and prosecution costs up to the hearing in all disciplinary cases. This includes all charges of the Office of the Attorney General, including, but not limited to, those for legal services, and includes charges by expert consultants. The board believes that the burden of paying for disciplinary cases should fall on those whose conduct requires investigation and prosecution, not upon the profession as a whole.

The board recognizes there may be situations where an individual licensee deserves a stronger penalty than the pharmacy for which he or she works, but the board also believes in holding a pharmacy owner, manager, and/or pharmacist-in-charge responsible for the acts of pharmacy personnel. Similarly, the board recognizes that in some cases a licensed premises may well be more culpable than any individual licensed by or registered with the board.

For purposes of these guidelines “board” includes the board and/or its designees.

FACTORS TO BE CONSIDERED IN DETERMINING PENALTIES

Section 4300 of the Business and Professions Code provides that the board may discipline the holder of, and suspend or revoke, any certificate, license or permit issued by the board.

In determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, factors such as the following should be considered:

1. actual or potential harm to the public
2. actual or potential harm to any consumer
3. prior disciplinary record, including level of compliance with disciplinary order(s)
4. prior warning(s), including but not limited to citation(s) and fine(s), letter(s) of admonishment, and/or correction notice(s)
5. number and/or variety of current violations
6. nature and severity of the act(s), offense(s) or crime(s) under consideration
7. aggravating evidence
8. mitigating evidence
9. rehabilitation evidence
10. compliance with terms of any criminal sentence, parole, or probation
11. overall criminal record
12. if applicable, evidence of proceedings for case being set aside and dismissed pursuant to Section 1203.4 of the Penal Code
13. time passed since the act(s) or offense(s)
14. whether the conduct was intentional or negligent, demonstrated incompetence, or, if the respondent is being held to account for conduct committed by another, the respondent had knowledge of or knowingly participated in such conduct
15. financial benefit to the respondent from the misconduct.

No single one or combination of the above factors is required to justify the minimum and/or maximum penalty in a given case, as opposed to an intermediate one.

MITIGATING EVIDENCE

A respondent is permitted to present mitigating circumstances at a hearing or in the settlement process and has the burden of demonstrating any rehabilitative or corrective measures he or she has taken. The board does not intend, by the following references to written statements, letters, and reports, to waive any evidentiary objections to the form or admissibility of such evidence. The respondent must produce admissible evidence in the form required by law in the absence of a stipulation to admissibility by the complainant.

The following are examples of appropriate evidence a respondent may submit to demonstrate his or her rehabilitative efforts and competency:

a. Recent, dated, written statements and/or performance evaluations from persons in positions of authority who have on-the-job knowledge of the respondent's current competence in the practice of pharmacy including the period of time and capacity in which the person worked with the respondent. Such reports must be signed under penalty of perjury and will be subject to verification by board staff.
b. Recent, dated, letters from counselors regarding the respondent's participation in a rehabilitation or recovery program, which should include at least a description and requirements of the program, a psychologist's diagnosis of the condition and current state of recovery, and the psychologist's basis for determining rehabilitation. Such letters and reports will be subject to verification by board staff.
c. Recent, dated, letters describing the respondent's participation in support groups, (e.g., Alcoholics Anonymous, Narcotics Anonymous, professional support groups, etc.). Such letters and reports will be subject to verification by board staff.
d. Recent, dated, laboratory analyses or drug screen reports, confirming abstention from drugs and alcohol. Such analyses and reports will be subject to verification by board staff.
e. Recent, dated, physical examination/ ~~or~~ assessment report(s) by a licensed physician, confirming the absence of any physical impairment that would prohibit the respondent from practicing safely. Such ~~assessments and~~ report(s) will be subject to verification by board staff.
f. Recent, dated, letters from probation or parole officers regarding the respondent's participation in and/or compliance with terms and conditions of probation or parole, which should include at least a description of the terms and conditions, and the officer's basis for determining compliance. Such letters and reports will be subject to verification by board staff.
g. Recent, dated, letters from persons familiar with respondent in either a personal or professional capacity regarding their knowledge of: the respondent's character; the respondent's rehabilitation, if any; the conduct of which the respondent is accused; or any other pertinent facts that would enable the board to better decide the case. Such letters must be signed under penalty of perjury and will be subject to verification by board staff.

TERMS OF PROBATION – ~~PHARMACIST/INTERN PHARMACIST~~ INDIVIDUAL LICENSEES (PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE)

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against the license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

For those licenses issued to individuals (pharmacists, intern pharmacists, pharmacy technicians, and designated representatives), the board has identified four (4) categories of violations and their associated recommended minimum and maximum penalties. These categories of violations are arranged in ascending order from the relatively minor (Category I) to the most serious (Category IV), although any single violation in any category, or any combination of violation(s) in one or more categories, may merit revocation. For pharmacy technicians and designated representatives, the board believes an order of revocation is typically the appropriate penalty when any grounds for discipline are established, and that if revocation is not imposed that a minimum Category III level of discipline should be imposed.

~~The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses~~.

~~Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive.~~ For each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation ~~of each listed statute or regulation~~. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; one year probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations which are relatively minor but are potentially harmful. These may include:

- violations ~~which are relatively minor but are potentially harmful~~ of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- ~~repeated violations of a relatively minor nature:~~ smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs, or controlled substances; and
- violation(s) of packaging requirements, security control requirements, or reporting requirements.

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4052.1 Skin Puncture by Pharmacist; Conditions Permitting~~
~~4052.5 Pharmacist May Select Different Form of Medication with Same Active Chemical Ingredients; Exceptions~~
~~4052.7 Repackage Previously Dispensed Drugs; Requirements~~
~~4053 Exemptee Supervisor of Manufacturer, etc.: Requirements~~
~~4054 Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices~~
~~4055 Sale of Devices to Licensed Clinics, etc.~~
~~4056 Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less~~
~~4057 Exceptions to Application of this Chapter~~
~~4058 Display of Original License~~
~~4062 Furnishing Dangerous Drugs During Emergency~~
~~4064 Emergency Refill of Prescription Without Prescription Authorization~~

~~4065 Injection Card System; Requirements of Administration~~
~~4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel~~
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~~Article 4. Requirements for Prescription~~

~~4070 Reduction of Oral or Electronic Prescription to Writing~~
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~~4077 Dispensing Dangerous Drug in Incorrectly Labeled Container~~

~~Article 5. Authority of Inspectors~~

~~4082 Names of Owners, Managers and Employees Open for Inspection~~

~~Article 6. General Requirements~~

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~~4103 Blood Pressure – Taking by Pharmacist~~

~~Article 7. Pharmacies~~

~~4114 Intern Pharmacist: Activities Permitted~~
~~4119 Furnish Prescription Drug to Licensed Health Care Facility – Secured~~
~~4119.1 Pharmacy May Provide Services to Health Facility~~
~~4119.5 Transfer or Repackaging Dangerous Drugs by Pharmacy~~
~~4121 Advertisement for Prescription Drug: Requirements; Restrictions~~
~~4122 Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests~~
~~4123 Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board~~
~~4124 Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies~~

~~Article 9. Hypodermic Needles and Syringes~~

~~4141 Furnishing Without License~~
~~4142 Prescription Required~~
~~4143 Exemption: Sale to Other Entity, Physician, etc.~~
~~4144 Industrial Use Exception~~
~~4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions~~
~~4148 Confiscation if Found Outside Licensed Premises~~
~~4149 Sale by Distributor~~

~~Article 10. Pharmacy Corporations~~

Article 11. Wholesalers and Manufacturers

Article 13. Non-Profit or Free Clinics

Article 14. Surgical Clinics

Article 15. Veterinary Food-Animal Drug Retailers

Article 17. Continuing Education

Article 18. Poisons

4240 Application of Act

Article 20. Prohibitions and Offenses

4341 Advertisement of Prescription Drugs or Devices
4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within

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1715.6 Reporting Drug Loss
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1717.4 Electronic Transmission of Prescriptions
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11201 Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements
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~~1707.15 Child-resistant containers.~~

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of controlled substances is involved). All

standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Category II discipline is recommended for violations with serious potential for harm, as well as for violations involving disregard for public safety or for the laws or regulations pertaining to pharmacy and/or to dispensing or distributing of dangerous drugs or controlled substances, violations that reflect on ethics, competence, or diligence, and criminal convictions not involving alcohol, dangerous drugs, or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;
- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;
- violation(s) of monitoring and reporting requirements with regard to chemically, mentally, or physically impaired licensees or employees;
- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs, or controlled substances;
- violation(s) of law governing dangerous drugs and controlled substances, including smaller cases of diversion or self-administration;
- unlawful possession(s) of dangerous drugs, controlled substances, hypodermic needles and syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drug(s) or device(s) via the internet without valid prescription(s);
- purchasing, trading, selling, or transferring dangerous drug(s) or devise(s) to or from unauthorized person(s);
- failure(s) to make required reports to board or other regulatory agencies, including CURES obligations and reporting to DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, clearly excessive furnishing of controlled substances, moral turpitude, dishonest, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs, or controlled substances;
- violating, or assisting in or abetting violation of, or conspiring to violate the laws and regulation governing pharmacy; and
- subverting or attempting to subvert an investigation conducted by the board.
- ~~violations with a serious potential for harm~~
- ~~violations which involve greater disregard for pharmacy law and public safety~~
- ~~violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.~~

Violations of the following codes are representative of this category:

BUSINESS AND PROFESSIONS CODE

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1793.1 Duties of a Pharmacist
1793.2 Duties of a Pharmacy Technician
1793.3 Other Non-Licensed Pharmacy Personnel
1793.7 Requirements for Pharmacies Employing Pharmacy Technicians
1793.8 Technicians in Hospitals with Clinical Pharmacy Programs

HEALTH AND SAFETY CODE

11103 Report of Theft, Loss, or Shipping Discrepancy
11150 Persons Authorized to Write or Issue a Prescription
11152 Nonconforming Prescriptions Prohibited
11154 Prescription, etc, Must Be for Treatment; Knowing Solicitation of Unlawful Prescription, etc.
11156 Prescribing, etc. Controlled Substances to Addict Only as Authorized
11164 Prescriptions for Schedule II, III, IV and V Controlled Substances: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substances
11166 Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited
11170 Prohibition on Prescribing, etc. Controlled Substance for Self
11179 Retention of Controlled Substance Prescription
11207 Only Pharmacist or Intern Authorized to Fill Prescription
11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
11350 Possession of Specified Controlled Substance
11377 Unlawful Possession of Specified Substance
11165(d) CURES Transmission
150204 Surplus Medication Collection and Distribution Program

~~**CODE OF FEDERAL REGULATIONS, TITLE 21**~~

~~1304.03 Persons required to keep records and file reports.~~
~~1304.04 Maintenance of records and inventories.~~
~~1304.11 Inventory requirements .~~
~~1304.21 General requirements for continuing records.~~
~~1304.22 Records for manufacturers.~~
~~1305.07 Special procedure for filling certain orders.~~
~~1305.13 Procedure for filling DEA Forms 222.~~
~~1306.04 Purpose of issue of prescription.~~
~~1306.06 Persons entitled to fill prescriptions.~~
~~1306.07 Administering or dispensing of narcotic drugs.~~
~~1306.11 Requirement of prescription.~~
~~1306.12 Refilling prescription.~~
~~1306.13 Partial filling of prescriptions.~~
~~1306.21 Requirement of prescription.~~
~~1306.22 Refilling of prescriptions.~~
~~1306.23 Partial filling of prescriptions.~~

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of controlled substances is involved). All standard terms and conditions and optional terms and conditions as appropriate.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or controlled substances, and most criminal convictions involving alcohol, dangerous drugs or controlled substances, and most criminal convictions involving alcohol, dangerous drugs, or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by electronic pedigree requirements for dangerous drugs;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;
- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- violation(s) of laws governing dangerous drugs and controlled substances, including repeat or serious diversion or self-administration;
- repeat or serious unlawful possession(s) of dangerous drugs, controlled substances, hypodermic needles or syringes, or drug paraphernalia;

- larger scale dispensing or furnishing or dangerous drug(s) or device(s) via the internet, without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) or devices(s);
- removal, sale, or disposal of embargoed dangerous drug(s) or device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) or device(s);
- resale(s) of preferentially priced drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;
- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) or controlled substance(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
  - ~~most criminal convictions involving dangerous drugs or controlled substances~~
  - ~~knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances~~
  - ~~fraudulent acts committed in connection with the licensee's practice~~
  - ~~drug shortages~~
  - ~~violation of a licensee's corresponding responsibility.~~

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4034 Pedigree~~
~~4051(a) Conduct Limited To Pharmacist~~
~~4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions~~
~~4059.5 Who May Order Dangerous Drugs or Devices: Exceptions~~

~~**Article 5. Authority of Inspectors**~~

~~4080 Stock of Dangerous Drugs and Devices Kept Open for Inspection~~
~~4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory~~
~~4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device~~

~~**Article 6. General Requirements**~~

~~4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records~~

~~**Article 7. Pharmacies**~~

4110 Licensed Required; Temporary Permit Upon Transfer of Ownership
4111 Restrictions on Prescriber Ownership

Article 11. Wholesalers and Manufacturers

4169(a)(2) to
4169(a)(5) Prohibited Acts

Article 15. Veterinary Food-Animal Retailers

4199 Labeling Requirements; Maintaining Prescription Records

Article 19. Disciplinary Proceedings

4301 Unprofessional Conduct - subsections (i) - (k) and (o)
4307 Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding
4308 Prohibited Association: Notification of Affected Licensees Known to Board

Article 20. Prohibitions and Offenses

4322 Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties
4323 Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug
4324 Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription
4325 Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank
4327 Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages
4329 Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs
4332 Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records
4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor
4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1707 Waiver Requirements for Off-Site Storage of Records
1718 Current Inventory Defined
1761(b) Erroneous or Uncertain Prescriptions
1771 Posting of Notice of Suspension

~~1772 Disciplinary Condition of Suspension~~
~~1773 Disciplinary Conditions of Probation of Pharmacist~~
~~1774 Disciplinary Conditions of Probation of Permit~~

~~HEALTH AND SAFETY CODE~~

~~11104 Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties~~
~~11105 False Statement in Report~~
~~11150 Persons Authorized to Write or Issue a Prescription~~
~~11153 Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation~~
~~11153.5 Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy~~
~~11157 No False or Fictitious Prescriptions~~
~~11162.5 Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty~~
~~11173 Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label~~
~~11174 Prohibition on Providing False Name or Address in Connection with Prescription, etc.~~
~~11351 Possession or Purchase for Sale of Specified Controlled Substance~~
~~11368 Forged or Altered Prescriptions~~
~~11375 Possession for Sale or Selling Specified Substance~~
~~11378 Possession for Sale~~
~~11550 Using or Being Under Influence of Controlled Substance~~
~~11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substances in a Skilled Nursing Facility~~
~~111295 Manufacturing, Selling, or Offering for Sale an Adulterated Drug or Device~~
~~111300 Unlawful to Adulterate a Drug~~
~~111305 Unlawful to Receive in Commerce an Adulterated Drug~~
~~111440 Unlawful Manufacturer, Selling a Misbranded Drug~~
~~111445 Unlawful for a Person to Misbrand~~
~~111450 Unlawful to Receive into Commerce a Drug that is Misbranded~~

CATEGORY IV

Penalty: Revocation

Category IV discipline (~~R~~revocation) is recommended for the most serious violations of laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or controlled substances. Violations in this category may include: ~~the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving:~~

- ~~possession for sale~~ violations involving possession for sale, transportation, importation, and/or use of a minor for unlawful sale of controlled substances;
- ~~transportation~~ criminal convictions involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs, or controlled substances; and
- repeated or serious example(s) of conduct described in Category I, Category II, or Category III.

- ~~importation~~
- ~~sale~~
- ~~use of a minor for the unlawful sale of controlled substances~~

Revocation is also recommended ~~when:~~ where a respondent fails to file a notice of defense to an Accusation or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.

- ~~a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation~~
- ~~a respondent violates the terms and conditions of probation from a previous disciplinary order~~
- ~~prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.~~

~~Violations of the following codes are representative of this category:~~

~~**HEALTH AND SAFETY CODE**~~

~~11352 Importing, Selling, Furnishing Controlled Substance~~
~~11353 Adult Inducing Minor to Violate Provisions~~
~~11379 Transporting, Importing, Selling Controlled Substance~~
~~11380 Adult Using, Soliciting or Intimidating Minor for Violation~~

MODEL DISCIPLINARY LANGUAGE - ~~PHARMACIST/INTERN PHARMACIST~~ INDIVIDUAL LICENSEES (PHARMACIST, INTERN PHARMACIST, PHARMACY TECHNICIAN, DESIGNATED REPRESENTATIVE)

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation

License number _____, issued to respondent _____,is revoked.

Respondent shall relinquish ~~his or her~~ [his/her] ~~wall~~ license, including any indicia of licensure issued by the board, ~~and pocket renewal license~~ to the board within 10 days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked license for three years from the effective date of this decision.

~~Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.~~

~~**Option:**~~ As a condition precedent to reinstatement of his or her revoked license, respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reapplication or reinstatement of his or her license unless otherwise ordered by the board.

Option: Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Suspension

As part of probation, respondent is suspended from the practice as a [insert license type] for _____ [day(s)/month(s)/year(s)] ~~of pharmacy for _____~~ beginning the effective date of this decision.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

During any such suspension, ~~R~~respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

Standard Stay/Probation Order

License number _____, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a [insert license type] license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Option: (Pharmacist Interns Only)
Should the board subsequently issue a license to practice as a pharmacist during the period of probation, said license shall be immediately revoked. The revocation of such license shall be stayed, and the probation imposed by this decision and order will continue. Respondent shall be subject to the same terms and conditions imposed by this disciplinary order. Notwithstanding this provision, the Board reserves the right to deny respondent's application for the pharmacist licensure exam. If the board issues a pharmacist license to respondent, the following additional terms and conditions shall be included as part of the disciplinary order:

Surrender

Respondent surrenders license number _____ as of the effective date of this decision. Respondent shall relinquish his or her ~~wall~~ license, including any indicia of licensure issued by the board, ~~and/or pocket renewal license~~ to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if ~~he or she~~ [he/she] ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not apply for any license, permit, or registration from the board for three years from the effective date of this decision. Respondent stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct

and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to taking and passing licensing examination(s) as well as fulfilling any education or experience requirements ~~the California Pharmacist Licensure Examination~~ prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that ~~he or she~~ [he/she] shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against licensee, _____. Respondent is required to report this reprimand as a disciplinary action.

License Reinstatement Order with Conditions Prior to Issuing License

It is hereby ordered that the petition for reinstatement filed by _____ is hereby granted and Petitioner's License No. _____ will be reinstated upon the following conditions precedent:

a. Petitioner shall take and pass the [North American Pharmacist Licensure Examination (NAPLEX) and/or the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)/Pharmacy Technician Certification Board exam] within one (1) year of the effective date of this order.

b. Petitioner must pay the fee in place at the time for these examinations.

c. Petitioner must pay a reinstatement fee in the amount of $_____.

Option: Petitioner pays the Board's cost recovery or fine amount owed to the Board in the amount of $_____.

Upon completion of the conditions precedent above, Petitioner's license shall be REINSTATED. Upon reinstatement, Petitioner's license shall be REVOKED. However, said revocation shall be STAYED, and Petitioner shall be placed on PROBATION for a period of _____ year(s)] under the following terms and conditions:

License Reinstatement

It is hereby ordered that the petition for reinstatement filed by _____ is hereby GRANTED and Petitioner's license shall be REINSTATED. Upon reinstatement, Petitioner's license shall be REVOKED. However, said revocation shall be STAYED, and Petitioner shall be placed on PROBATION for a period of _____ years under the following terms and conditions:

~~Adoption of Stipulation~~

~~It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Obey All Laws
2. Report to the Board
3. Interview with the Board
4. Cooperate with Board Staff
5. Continuing Education
6. Reporting of Employment and Notice to Employers
7. Notification of Change(s) in Name, Employment, Address(es), or Phone Number(s)
~~7.~~8. ~~No Supervision of Interns, Serving as Pharmacist-In-Charge (PIC), or Serving as a Consultant~~ Restrictions on Supervision and Oversight of Licensed Facilities
~~8~~ 9. Reimbursement of Board Costs
~~9~~ 10. Probation Monitoring Costs
~~10~~ 11. Status of License
~~11~~ 12. License Surrender While on Probation/Suspension
~~12. Notification of a Change in Name, Residence Address, Mailing Address or Employment~~
13. Certification Prior to Resuming Work
14. Notification of Departure
~~13.~~ 15. ~~Tolling of Probation~~ License Practice Requirement - Tolling
~~14.~~ 16. Violation of Probation
~~15.~~ 17. Completion of Probation

OPTIONAL CONDITIONS

18. Suspension
~~16.~~ 19. Restricted Practice
~~17.~~ 20. Pharmacist Examination
~~18.~~ 21. ~~Mental Health Examination~~ Clinical Diagnostic Evaluation
~~19.~~ 22. Psychotherapy
~~20.~~ 23. Medical Evaluation
~~21.~~ 24. Pharmacists Recovery Program (PRP)
~~22.~~ 25. ~~Random Drug Screening~~ Drug and Alcohol Testing
~~23.~~ 26. Abstain from Drugs and Alcohol ~~Use~~
~~24.~~ 27. Prescription Coordination and Monitoring of Prescription Use
28. Facilitated Group Recovery and/or Support Meetings
29. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
30. Work Site Monitor
~~25.~~ 31. Community Service Program
~~26.~~ 32. Restitution
~~27.~~ 33. Remedial Education
~~28. Pharmacy Self-Assessment Mechanism (PSAM)~~
~~29.~~ 34. Intern Pharmacist Experience
~~30.~~ 35. Supervised Practice
~~31. No Supervision of Ancillary Personnel~~
~~32.~~36. No Ownership or Management of Licensed Premises
~~33.~~37. Separate File of Controlled Substances Records
~~34.~~38. Report of Controlled Substances
~~35.~~39. No Access to Controlled Substances
~~36.~~40. Criminal Probation/Parole Reports
~~37. Consultant for Owner or Pharmacist-In-Charge~~
41. Tolling of Suspension

~~39.~~42. Surrender of DEA Permit
~~40.~~43. Ethics Course

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of ~~his or her~~ [his/her] probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Continuing Education (Pharmacists Only)

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Reporting of Employment and Notice to Employers

During the period of probation, respondent shall provide the board with written consent authorizing communication with all employers and shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of undertaking any new employment, respondent shall report to the board in writing the name, physical address, and mailing address of all of [his/her] employer(s), and the name(s) and telephone number(s) of all of [his/her]direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, or other compliance supervisor(s). Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause (a) ~~his or her~~ [his/her] direct supervisor, (b) his or her pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor, ~~(including each new pharmacist-in-charge employed during respondent's tenure of employment)~~ and (c) the owner or owner representative of his or her employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the respondent's responsibility to ensure that these acknowledgement(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. ~~It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.~~

If respondent works for or is employed by or through ~~a pharmacy~~ an employment service, respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board, of the decision in case number _____, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity ~~his or her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each licensed entity~~. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through ~~a pharmacy~~ an employment service, respondent shall cause the person(s) described in (a), (b), and (c) above ~~his or her direct supervisor with the pharmacy~~ at the employment service to report to the board in writing

acknowledging that he or she has read the decision in case number _____, and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board ~~his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board~~.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

> "Employment" within the meaning of this provision ~~shall~~ includes any full-time, part-time, temporary, relief, or employment/management service position as a [insert license type], or any position for which a [insert license type] license ~~or pharmacy management service as a pharmacist or any position for which a pharmacist license~~ is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

Option (to be used for pharmacist interns): During any period of probation, respondent shall shall sign and return to the board a written consent authorizing the board or its designee to communicate with the school of pharmacy representatives including the clinical rotation coordinator authorizing those individuals to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

7. Notification of Change(s) in Employment, Name, Address(es), or Phone Number(s)[1]

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

~~7~~8. ~~No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant~~ Restrictions on Supervision and Oversight of Licensed Facilities[2] (Pharmacists or Designated Representatives only)

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, ~~or~~ designated representative-in-charge, or other compliance supervisor of any entity licensed by the board, nor serve as a consultant ~~unless otherwise specified in this order~~. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

[1] This term was renamed and renumbered from previous term 12.

[2] This term was renamed and consolidated with two additional terms: No Supervision of Ancillary Personnel and Consultant for Owner of Pharmacist-in-Charge.

Option 1: During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the board. Assumption of any such unauthorized ancillary personnel supervision responsibilities shall be considered a violation of probation.

Option 2a: During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor of any single entity licensed by the board, but only if respondent or that entity retains, at his/her/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a [monthly/quarterly] basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of his or her supervisory position. Respondent may serve in such a position at only one entity licensed by the board. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

Option 2b: During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor of any single entity licensed by the board, but only if respondent or that entity retains, at his/her/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a [monthly/quarterly] basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of his or her supervisory position. Respondent may serve in such position at only one entity licensed by the board, and only at an entity of which [he/she] is the sole owner. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

Option 2c: During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, or other compliance supervisor of any single entity licensed by the board, but only if respondent or that entity retains, at his/her/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a [monthly/quarterly] basis for compliance by respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by respondent with the obligations of his or her supervisory position. Respondent may serve in such position at only one entity licensed by the board, and only if respondent is already serving in such a position at the time of the effective date of this decision. The consultant shall be a pharmacist licensed by and not on probation with the board, who has been approved by the board or its designee to serve in this position. Respondent shall submit the name of the

proposed consultant to the board or its designee for approval within thirty (30) days of the effective date of the decision. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

~~8~~9. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

Option: Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation. A payment plan must be submitted to the board within 30 days of the effective date of the decision for board consideration.

~~The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.~~

~~9~~10. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

~~10~~11. Status of License

Respondent shall, at all times while on probation, maintain an active, current [insert license type] license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current [insert license type] license shall be considered a violation of probation.

If respondent's [insert license type] license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's [insert license type] license shall be subject to all terms and conditions of this probation not previously satisfied.

~~11~~12. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her [insert license type] license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the [insert license type] license, respondent will no longer be subject to the terms and conditions of

probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket and/or wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

~~**12. Notification of a Change in Name, Residence Address, Mailing Address or Employment**~~

~~Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number(s).~~

~~Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.~~

13. Certification Prior to Resuming Work (Pharmacy Technicians Only)[3]

Respondent shall be suspended, and shall not work as a pharmacy technician nor work in any capacity in a pharmacy, until [he/she] has been certified as defined by Business and Professions Code section 4202, subdivision (a)(4), has submitted proof of certification to the board, and has been notified by the board or its designee that [he/she] may begin work. Failure to achieve certification within six (6) months shall be considered a violation of probation. Respondent shall not resume working as a pharmacy technician until notified by the board.

During any such suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs~~)~~ which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

During any such suspension, respondent shall not engage in any activity that requires licensure as a pharmacy technician. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices or controlled substances.

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

[3] This probationary term is not new, but is rather being moved from the "Model Disciplinary language - - Pharmacy Technician" Standard Terms and Conditions for purposes of consolidation.

Option: Respondent shall maintain an active, current certification as defined by Business and Professions Code section 4202, subdivision (a)(4), for the entire period of probation, and shall submit proof of re-certification or renewal of certification to the board within ten (10) days of receipt. Failure to maintain active, current certification or to timely submit proof of same shall be considered a violation of probation.

14. Notification of Departure[4]

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

~~30.~~ 15. Supervised Practice (Pharmacists & Designated Representatives Only)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's practice supervisor. As part of the documentation submitted, respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. This level will be determined by the board or its designee, will be communicated to the respondent on or before the effective date of this decision and shall be one of the following:

Continuous – At least 75% of a work week
Substantial - At least 50% of a work week
Partial - At least 25% of a work week
Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Respondent may practice only under the required level of supervision by an approved practice supervisor. If, for any reason, including change of employment, respondent is no longer supervised at the required level by an approved practice supervisor, within ten (10) days of this change in supervision respondent shall submit to the board or its designee, for prior approval, the name of a [insert license type] licensed by and not on probation with the board, to serve as respondent's replacement practice supervisor. As part of the documentation submitted, respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number [insert case number], and is familiar with the terms and conditions imposed thereby, including the level of supervision required.

Any of the following shall be considered a violation of probation: failure to timely nominate either an initial or a replacement practice supervisor; failure to cause the practice supervisor to timely report to the board in writing acknowledging the decision, terms and conditions, and supervision level; practicing in the absence of an approved practice supervisor after lapse of the nomination period; and/or failure to adhere to the level of supervision required by the board or its designee. If any of these obligations or prohibitions is not met, respondent shall be

[4] This probationary term is not new, but is rather being moved from the "Model Disciplinary language - - Pharmacy Technician" for purposes of consolidation.

automatically suspended from practice as a [insert license type] and may not resume such practice until notified by the board or its designee in writing..

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices or controlled substances.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs or devices or controlled substances.

Failure to comply with any such suspension shall be considered a violation of probation.

~~13.~~15. ~~Tolling of Probation~~ License Practice Requirement - Tolling

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a ~~pharmacist~~ [insert license type] in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless the respondent is notified in writing by the board or its designee.

~~Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of _____ hours per calendar month in California~~, If respondent does not practice as a [insert license type] in California for a minimum of _____ hours in any calendar month, for any reason (including vacation), respondent shall ~~must~~ notify the board in writing within ten (10) days of the ~~cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice.~~ conclusion of that calendar month. This notification shall include at least: the date(s), locations(s), and hours of last practice; the reason(s) for the interruption or decline in practice; and the anticipated date(s) on which respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a [insert license type] in California for a minimum of _____ hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

> ~~"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least _____ hours, as defined by Business and~~

~~Professions Code section 4000 et seq . "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least _____ hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.~~

Option 1: As a condition precedent to successful completion of probation, during the period of probation respondent shall practice as a [insert license type] in a licensed _____ in California that dispenses dangerous drugs for a minimum of one (1) year. After the first year or probation, the board or its designee may consider a modification of this requirement. Failure to comply with this requirement (or as modified) shall be considered a violation of probation. ~~Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.~~

Option 2: **(First-year pharmacist interns only)** During respondent's first academic year of enrollment in a school or college of pharmacy, no minimum practice hours shall be required. Instead, respondent shall report to the board quarterly in writing, in a format and schedule as directed by the board or its designee, on [his/her] compliance with academic and vocational requirements, and on [his/her] academic progress. This exemption shall apply only once, and only during respondent's first academic year. Respondent must comply with all other terms and conditions of probation, unless notified in writing by the board or its designee.

~~14.~~16. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. ~~Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license.~~ If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

~~15.~~17. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

18. Suspension

As part of probation, respondent is suspended from practice as a [insert license type] for _____ [day(s)/month(s)/year(s)] beginning the effective date of this decision.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices or controlled substances.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances.

Failure to comply with any such suspension shall be considered a violation of probation.

Option 1: During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during the period of suspension shall be considered a violation of probation, and shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation, unless notified in writing by the board or its designee.

Respondent shall notify the board or its designee in writing within ten (10) days of any departure from California, for any period, and shall further notify the board or its designee in writing within ten (10) days of return. Failure to timely provide such notification(s) shall be considered a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board or its designee that the period of suspension has been satisfactorily completed.

~~16.~~19. Restricted Practice

Respondent's practice as a [insert license type] ~~of pharmacy~~ shall be restricted to [specify setting or type of practice] for the first _____ year(s) of probation. Respondent shall submit ~~proof satisfactory~~ to the board or its designee in writing,of compliance with this term of probation.

Option: Respondent shall not prepare, oversee, or participate in the preparation of injectable sterile products during the first _____ year(s) of probation. Upon request, respondent ~~Respondent~~ shall submit to the board or its designee on writing, satisfactory proof ~~satisfactory~~ of compliance with this restriction, including but not limited to a written acknowledgment of this restriction signed by (a) respondent's direct supervisor, (b) the pharmacist-in-charge, and (c) the owner or owner representative of his or her employer, which explains whether the workplace in question compounds drug products and how this restriction will be enforced ~~term of probation~~. Failure to abide by this restriction or to timely submit proof to the board or its designee ~~of~~

~~compliance therewith~~ shall be considered a violation of probation.

~~17.~~20. Pharmacist Examination (Pharmacists Only)

Respondent shall take and pass the [California Pharmacist Jurisprudence Examination (CPJE) and/or the North American Pharmacist Licensure Examination (NAPLEX)] within six (6) months of the effective date of this decision. If respondent fails to take and pass the examination(s) within six (6) months after the effective of this decision, respondent shall be automatically suspended from practice. Respondent shall not resume the practice of pharmacy until ~~he or she~~ [he/she] takes and passes the [CPJE and/or NAPLEX] and is notified, in writing, that ~~he or she~~ [he/she] has passed the examination(s) and may resume practice. Respondent shall bear all costs of the examination(s) required by the board.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devises and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices and controlled susbtances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

If respondent fails to take and pass the [CPJE and/or NAPLEX] after four attempts, respondent shall successfully complete, at a minimum, sixteen (16) additional semester units of pharmacy education as approved by the board. The respondent shall submit in writing to the board or its designee satisfactory proof of completion of sixteen (16) additional semester units of pharmacy education. Failure to complete coursework or provide proof of such completion as required shall be considered a violation of probation.

Failure to take and pass the examination(s) within ~~one (1) year~~ six (6) months of the effective date of this decision shall be considered a violation of probation.

~~18.~~20. ~~Mental Health Examination~~ Clinical Diagnostic Evaluation (Appropriate for those cases where evidence demonstrates that ~~mental illness~~ psychiatric disorders (mental illness, emotional disturbance, gambling addiction), substance use, or disability was a contributing cause of the violation(s).)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter if ~~as may be~~ required by the board or its designee, respondent shall undergo, at ~~his or her~~ [his/her] own expense, ~~psychiatric~~ clinical diagnostic evaluation(s) by a ~~board-appointed or board-approved~~ licensed ~~mental health~~ practitioner selected or approved prior to the evaluation by the board or its designee. The approved evaluator shall be provided with a copy of the board's [accusation, ~~or~~ petition to revoke probation, or other pleading] and decision. Respondent shall sign a release authorizing the evaluator to furnish the board with a current diagnosis and a written report regarding the respondent's judgment and ability to function independently as a ~~pharmacist~~ [insert license type] with safety to the public. ~~Respondent shall comply with all the recommendations of the evaluator if directed by the board or its designee.~~ If the evaluator recommends restrictions or conditions on respondent's practice, including but not limited to, other terms and conditions listed in these guidelines (e.g., required psychotherapy, prescription coordination and monitoring, restricted practice), the board or its designee may by written notice to respondent adopt these restrictions or conditions as additional probation terms and conditions, violation of which shall be considered a violation of probation.
~~If the evaluator recommends, and the board or its designee directs, respondent shall undergo psychotherapy. Within thirty (30) days of notification by the board that a recommendation for psychotherapy has been accepted, respondent shall submit to the board or its designee, for prior approval, the name and qualification of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof by the board, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment therewith, submit the name of a replacement licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.~~

~~Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's expense, a mental health evaluation by a separate board-appointed or board-approved evaluator. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.~~

~~Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's [accusation or petition to revoke probation] and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.~~

If at any time the approved evaluator or therapist determines that respondent is unable to practice safely or independently as a pharmacist, the licensed mental health practitioner shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be

automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

Option 1: (Appropriate for those cases where evidence demonstrates substance abuse**)**: The evaluation(s) shall be conducted in accordance with acceptable professional standards for alcohol or substance abuse clinical diagnostic evaluations. The written report(s) shall set forth, at least, the opinions of the evaluator as to: whether respondent has an alcohol or substance abuse problem; whether respondent is a threat to him/herself or others; and recommendations for alcohol or substance abuse treatment, practice restrictions, or other steps related to respondent's rehabilitation and safe practice. If the evaluator determines during the evaluation process that respondent is a threat to him/herself or others, the evaluator shall notify the board within twenty-four (24) hours.

Commencing on the effective date of this decision, respondent is suspended from practice and shall not practice as a [insert license type] until:

- Respondent has undergone and completed clinical diagnostic evaluation(s);
- The report(s) of the evaluation(s) has/have been received by the board or its designee;
- One or more report(s) has concluded that respondent is safe to return to practice as a [insert license type];
- Respondent has submitted to observed bodily fluid testing for the presence of alcohol, dangerous drugs, or controlled substances [pursuant to Term and Condition 24] at least twice per week for at least thirty (30) days;
- During the testing period, respondent has not had a confirmed positive test result for alcohol, or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment, for at least thirty (30) days;
- The board or its designee has determined that respondent is safe to return to either full-time or part-time practice as a [insert license type], after considering the evaluation report(s), the results of the fluid testing, and criteria including the license type, respondent's history, respondent's documented period of sobriety or documented time since last use, respondent's scope and pattern of use, respondent's treatment history, respondent's medical history and current medical condition, the nature, duration, and severity of respondent's alcohol or substance abuse, and whether respondent is a threat to him/herself or others; and
- Respondent receives written notice from the board or its designee that practice may resume.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and controlled substances.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or

be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs or devices or controlled substances.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances.

Option 2: Commencing on the effective date of this decision, respondent is suspended from practice and shall not ~~engage in the practice of pharmacy~~ practice as a [insert license type] until ~~notified in writing by the board that respondent has been deemed psychologically fit to practice pharmacy safely, and the board or its designee approves said recommendation~~ the evaluator recommends that respondent return to practice, this recommendation is accepted by the board or its designee, and respondent receives written notice from the board or its designee that practice may resume.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices ~~and~~ or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

~~(Option language to be used in addition to standard language)~~

Option 3: If recommended by the~~ evaluating licensed mental health practitioner and approved by the board, respondent shall be suspended from practicing pharmacy until respondent's treating therapist recommends, in writing, stating the basis therefor, that respondent can safely practice pharmacy, and the board or its designee approves said recommendation.~~ evaluator, the board or its designee may suspend respondent from practice as a [insert license type] by providing written notice of suspension to the respondent. Upon suspension, respondent shall not resume practice as a [insert license type] until: 1) another evaluation done at respondent's expense by a licensed practitioner selected or approved by the board or its designee; 2) the evaluator recommends that respondent return to practice; 3) the board or its designee accepts

the recommendation; 4) and the board notifies the respondent in writing that practice may resume.

The report(s) from any such additional evaluation(s) shall be provided to the board or its designee in writing by the evaluator no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed thirty (30) days.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices or ~~and~~ controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

~~19.~~21. Psychotherapy (Appropriate for those cases where the evidence demonstrates ~~mental illness~~ psychiatric disorders (mental illness, emotional disturbance, gambling addiction) or alcohol or drug abuse was involved in the violation(s).)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, the name and qualifications of a licensed mental health practitioner of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved licensed mental health practitioner. Should respondent, for any reason, cease treatment with the approved licensed mental health practitioner, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement psychotherapist or licensed mental health practitioner of respondent's choice to the board for its prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of psychotherapy with the approved replacement. Failure to comply with any requirement or deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent licensed mental health practitioner, respondent shall undergo and continue treatment with that therapist, at respondent's own expense, until the therapist recommends in writing to the board, and the board or its designee agrees by way of a

written notification to respondent, that no further psychotherapy is necessary. Upon receipt of such recommendation from the treating therapist, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a mental health evaluation by a board-appointed or board-approved psychiatrist or psychologist. If the approved evaluator recommends that respondent continue psychotherapy, the board or its designee may require respondent to continue psychotherapy.

Psychotherapy shall be at least once a week unless otherwise approved by the board. Respondent shall provide the therapist with a copy of the board's accusation and decision no later than the first therapy session. Respondent shall take all necessary steps to ensure that the treating therapist submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and such other information as may be required by the board or its designee.

If at any time the treating therapist determines that respondent cannot practice safely or independently, the therapist shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices or ~~and~~ controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances

~~During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with any such ~~this~~ suspension shall be considered a violation of probation.

~~20.~~22. **Medical Evaluation** (Appropriate for those cases where the evidence demonstrates that the respondent has had a physical problem/disability which was a contributing cause of the violations and which may affect the respondent's ability to practice.)

Within thirty (30) days of the effective date of this decision, and on a periodic basis thereafter as may be required by the board or its designee, respondent shall undergo a medical evaluation, at respondent's own expense, by a board-appointed or board-approved physician who shall furnish a medical report to the board. The approved physician shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the physician to furnish the board with a current diagnosis and a written report regarding the respondent's ability to function independently as ~~a pharmacist~~ [insert license type] with safety to the public. Respondent shall comply with all the recommendations of the physician if directed by the board or its designee.

If the physician recommends, and the board or its designee directs, that respondent undergo medical treatment, respondent shall, within thirty (30) days of written notice from the board, submit to the board or its designee, for prior approval, the name and qualifications of a licensed physician of respondent's choice. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved physician. Should respondent, for any reason, cease treatment with the approved physician, respondent shall notify the board immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician of respondent's choice to the board or its designee for prior approval. Within thirty (30) days of approval thereof, respondent shall submit documentation to the board demonstrating the commencement of treatment with the approved replacement. Failure to comply with any deadline stated by this paragraph shall be considered a violation of probation.

Upon approval of the initial or any subsequent physician, respondent shall undergo and continue treatment with that physician, at respondent's own expense, until the treating physician recommends in writing to the board, and the board or its designee agrees by way of a written notification to respondent, that no further treatment is necessary. Upon receipt of such recommendation from the treating physician, and before determining whether to accept or reject said recommendation, the board or its designee may require respondent to undergo, at respondent's own expense, a medical evaluation by a separate board-appointed or board-approved physician. If the approved evaluating physician recommends that respondent continue treatment, the board or its designee may require respondent to continue treatment.

Respondent shall take all necessary steps to ensure that any treating physician submits written quarterly reports to the board concerning respondent's fitness to practice, progress in treatment, and other such information as may be required by the board or its designee.

If at any time an approved evaluating physician or respondent's approved treating physician determines that respondent is unable to practice safely or independently as a ~~pharmacist~~ [insert license type], the evaluating or treating physician shall notify the board immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice until notified by the board that practice may be resumed.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or

be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices or ~~and~~ controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)
Option 1: Commencing on the effective date of this decision, respondent shall not engage in the practice ~~of pharmacy~~ as a [insert license type] until notified in writing by the board that respondent has been deemed medically fit to practice safely and independently, and the board or its designee approves said recommendation.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice ~~pharmacy~~ as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

(Option language to be used in addition to standard language)
Option 2: If recommended by the evaluating physician and approved by the board, respondent shall be suspended from practicing ~~pharmacy~~ as a [insert license type] until the treating physician recommends, in writing, stating the basis therefor, that respondent can safely and independently resume the practice of a pharmacist, and the board or its designee approves said

recommendation. Respondent shall not resume practice until notified by the board that practice may be resumed.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice ~~pharmacy~~ as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs ~~and~~ or devices or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

~~21.~~23. Pharmacists Recovery Program (PRP) (Appropriate for those cases where evidence demonstrates substance abuse ~~chemical dependency (alcohol, drugs),~~ or psychiatric disorders (mental illness, emotional disturbance, gambling addiction) (Pharmacists and Pharmacist Interns Only)

By no later than ten (10) days after ~~Within thirty (30) days of~~ the effective date of this decision, respondent shall have completed all of the following: contacted the Pharmacists Recovery Program (PRP) for evaluation; enrolled in the PRP; completed, signed, and returned the treatment contract plus any addendums required or suggested by the PRP; successfully completed registration for any drug or alcohol testing mandated by the treatment contract and/or by enrollment in the PRP; and begun compliance with the drug or alcohol testing protocol(s). ~~contact the Pharmacists Recovery Program (PRP) for evaluation, and shall immediately thereafter enroll, successfully participate in, and complete the treatment contract and any subsequent addendums as recommended and provided by the PRP and as approved by the board or its designee~~. Respondent shall successfully participate in the PRP and complete the treatment contract and any addendums required or suggested by the PRP and approved by the board or its designee. The costs for PRP participation shall be borne by the respondent.

If respondent is currently enrolled in the PRP, said participation is now mandatory and as of the effective date of this decision is no longer considered a self-referral under Business and Professions Code section 4362~~(c)~~ (a)(2). Respondent shall successfully participate in and complete his or her current contract and any subsequent addendums with the PRP.

Failure to timely contact or enroll in the PRP, complete the treatment contract and any addendums, complete testing registration, comply with testing, and/or successfully participate in and complete the treatment contract and/or any addendums, shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent shall not resume practice until notified in writing by the board or its designee.

Probation shall be automatically extended until respondent successfully completes the PRP. Any person terminated from the PRP program shall be automatically suspended by the board. Respondent may not resume the practice of pharmacy until notified by the board in writing.

Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall result in the automatic suspension of practice by respondent and shall be considered a violation of probation. Respondent may not resume the practice of pharmacy until notified by the board in writing.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice ~~pharmacy~~ as a [insert license type] nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs ~~and~~ or devices or controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with any such ~~this~~ suspension shall be considered a violation of probation.

Respondent shall pay administrative fees as invoiced by the PRP or its designee. Fees not timely paid to the PRP shall constitute a violation for probation. The board will collect unpaid administrative fees as part of the annual probation monitoring costs if not submitted to the PRP.

(Option language to be used in addition to standard language)
Option: Respondent shall work in a pharmacy setting with access to controlled substances for six (6) consecutive months before successfully completing ~~probation~~ the PRP. If respondent fails to do so, probation shall be automatically extended until this condition has been met. Failure to satisfy this condition within six (6) months beyond the original date of expiration of the term of probation shall be considered a violation of probation.

~~22.~~ 24. ~~Random Drug Screening~~ Drug and Alcohol Testing (~~If PRP provision is required, this term is also to be included to allow for continued fluid monitoring by the Board in cases where a respondent successfully completes the PRP before completion of the probation period; terms is also appropriate for those cases where the evidence demonstrates that the respondent may have a problem with chemical dependency (drugs, alcohol) but where the PRP is not required~~ (Appropriate for those cases where the evidence demonstrates substance use.)

Respondent, at ~~his or her~~ [his/her] own expense, shall participate in random testing~~, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program~~ as directed by the board or its designee~~. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times, respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples~~ for the detection of alcohol, ~~narcotics, hypnotics~~controlled substances, and dangerous drugs~~. or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of practice of pharmacy by respondent. Respondent may not resume the practice of pharmacy until notified by the board in writing.~~ Testing protocols may include biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other testing protocols as directed by the board or its designee. All testing must be pursuant to an observed testing protocol, unless respondent is informed otherwise in writing by the board or its designee. Respondent may be required to participate in testing for the entire probation period and frequency of testing will be determined by the board or its designee. The testing frequency will generally range between 36 – 104 tests per year.

By no later than thirty (30) days after the effective date of this decision, respondent shall have completed all of the following tasks: enrolled and registered with an approved drug and alcohol testing vendor; provided that vendor with any necessary information and documentation, and any information necessary for payment by respondent; commenced testing protocols, including all required contacts with the testing vendor to determine testing date(s); and begun testing. At all times, respondent shall fully cooperate with the testing vendor, and with the board or its designee, with regard to enrollment, registration, and payment for, and compliance with, testing. Any failure to cooperate timely shall be considered a violation of probation.

Respondent may be required to test on any day, including weekends and holidays. Respondent is required to make daily contact with the testing vendor to determine if a test is required, and if a test is required must submit to testing on the same day.

Any detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, may cause the board or its designee to increase the frequency of testing, in addition to any other action including but not limited to further disciplinary action.

Prior to any vacation or other period of absence from the geographic area of the approved testing vendor, respondent shall seek and receive approval from the board or its designee of an alternate testing vendor in the geographic area to be visited or resided in by respondent. Upon

approval, respondent shall enroll and register with the approved alternate drug testing vendor, provide that alternate vendor with any necessary information and documentation, including any necessary payment by respondent. During the period of visitation or residence in the alternate geographic area, respondent shall commence testing protocols with the alternate vendor, including required daily contacts with the testing vendor to determine if testing is required, and required testing. Any failure to timely seek or receive approval from the board or its designee, or to timely enroll and register with, timely commence testing protocols with, or timely undergo testing with, the alternate testing vendor, shall be considered a violation of probation.

Upon detection through testing of a controlled substance or dangerous drug, the board or its designee may require respondent to timely provide documentation from a licensed practitioner authorized to prescribe the detected substance demonstrating that the substance was administered or ingested pursuant to a legitimate prescription issued as a necessary part of treatment. All such documentation shall be provided by respondent within ten (10) days of being requested.

Any of the following shall be considered a violation of probation and shall result in respondent being immediately suspended from practice as a [insert license type] until notified by the board in writing that [he/she] may resume practice: failure to timely complete all of the steps required for enrollment/registration with the drug testing vendor, including making arrangements for payment; failure to timely commence drug testing protocols; failure to contact the drug testing vendor as required to determine testing date(s); failure to test as required; failure to timely supply documentation demonstrating that a detected substance was taken pursuant to a legitimate prescription issued as a necessary part of treatment; and/or detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment. In the event of a suspension ordered after detection through testing of alcohol, or of a controlled substance or dangerous drug absent documentation that the detected substance was taken pursuant to a legitimate prescription and a necessary treatment, the board or its designee shall inform respondent of the suspension and inform [him/her] to immediately leave work, and shall notify respondent's employer(s) and work site monitor(s) of the suspension.[5]

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and controlled substances. ~~Respondent shall not resume practice until notified by the board.~~

During any such suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a ~~pharmacist~~ [insert license type]. Respondent shall not direct or control any aspect of the practice of pharmacy, or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

2. The Terms of Probation Designated Representative are now consolidated into "Terms of Probation – Individual Licensees."

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

~~23.~~25. Abstain from Drugs and Alcohol ~~Use~~

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs, or ~~and~~ their associated paraphernalia, except when possessed or used pursuant to a legitimate prescription issued as a necessary part of treatment. ~~the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation.~~ Respondent shall ensure that ~~he or she~~ [he/she] is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, dangerous drugs or controlled substances, or their associated paraphernalia ~~not supported by~~ for which a legitimate prescription has been issued as a necessary part of treatment, ~~the documentation timely provided~~, ~~and/or~~ or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

~~24.~~26. Prescription Coordination and Monitoring of Prescription Use (Appropriate for those cases where the evidence demonstrates substance abuse ~~chemical dependency (alcohol, drugs),~~ or psychiatric disorders (mental illness, emotional disturbance, gambling addiction)

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board, for its prior approval, the name and qualifications of a single physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice, who shall be aware of the respondent's history [with the use of alcohol, controlled substances, and/or dangerous drugs, and/or of mental illness, and/or of gambling addiction] and who will coordinate and monitor any prescriptions for respondent for dangerous drugs, controlled substances or mood-altering drugs. The approved practitioner shall be provided with a copy of the board's [accusation or petition to revoke probation] and decision. A record of this notification must be provided to the board upon request. Respondent shall sign a release authorizing the practitioner to communicate with the board or its designee about respondent's treatment(s). The coordinating physician, nurse practitioner, physician assistant, or psychiatrist shall report to the board on a quarterly basis for the duration of probation regarding respondent's compliance with this condition. If any substances considered addictive have been prescribed, the report shall identify a program for the time limited use of any such substances. The board or its designee may require that the single coordinating physician, nurse practitioner, physician assistant or psychiatrist be a specialist in addictive medicine, or consult a specialist in addictive medicine. Should respondent, for any reason, cease supervision by the approved practitioner, respondent shall notify the board or its designee immediately and, within thirty (30) days of ceasing treatment, submit the name of a replacement physician, nurse practitioner, physician assistant, or psychiatrist of respondent's choice to the board or its designee for its prior approval. Failure to timely submit the selected practitioner or replacement practitioner to the board or its designee for approval, or to ensure the required reporting thereby on the quarterly reports, shall be

considered a violation of probation.

If at any time an approved practitioner determines that respondent is unable to practice safely or independently as a ~~pharmacist~~ [insert license type], the practitioner shall notify the board or its designee immediately by telephone and follow up by written letter within three (3) working days. Upon notification from the board or its designee of this determination, respondent shall be automatically suspended and shall not resume practice as a [insert license type] until notified by the board or its designee that practice may be resumed.

During any such suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer, or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs ~~and~~ or devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs or devices and controlled substances. Respondent shall not resume practice until notified by the board.

During any such suspension, respondent shall not engage in any activity that requires the professional judgment and/or licensure as a [insert license type] ~~of a pharmacist~~. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs or devices or controlled substances. ~~Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

Failure to comply with any such ~~this~~ suspension shall be considered a violation of probation.

~~25.~~27. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free [insert type of service e.g., health-care related services] on a regular basis to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board or its designee demonstrating commencement of the community service program. ~~A record of this notification must be provided to the board upon request.~~ Respondent shall report on progress with the community service program in the quarterly reports and provide satisfactory documentary evidence of such progress to the board or its designee upon request. Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

~~26.~~28. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

~~27.~~29. Remedial Education

Within [thirty (30), sixty (60), ninety (90)] days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to [the grounds for discipline]. The program of remedial education shall consist of at least _____ hours, which shall be completed within _____ months/year at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at ~~his or her~~ [his/her] own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

Option: Respondent shall be restricted from the practice of [areas where a serious deficiency has been identified] until the remedial education program has been successfully completed.

~~**28. Pharmacy Self-Assessment Mechanism**~~

~~Within the first year of probation, respondent shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the board demonstrating he/she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes.~~

~~Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation.~~

~~**Option A:** Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee.~~

~~**Option B:** (This term must be accompanied by the "Remedial Education" term. [Include/Modify Remedial Education Term to Conform].) Respondent shall waive any rights to confidentiality and provide examination results to the board or its designee. Based on the results of the examination, the board shall determine which courses are appropriate for remedial education~~.

~~29.~~ 30. Intern Pharmacist Experience (Pharmacist Interns Only)

Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a pharmacy intern training program consisting of _____ hours to be served as an intern pharmacist in a community and/or institutional pharmacy as directed. Respondent shall successfully complete the intern hours within the first year of probation and shall, by no later than one (1) year and ten (10) days from the effective date of this decision, submit proof satisfactory to the board of completion of this experience signed under penalty of perjury by both the respondent and supervising pharmacist. Failure to timely complete or document the required intern experience shall be considered a violation of probation.

~~30.Supervised Practice~~

~~During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his or her license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:~~

~~Continuous – At least 75% of a work week~~
~~Substantial - At least 50% of a work week~~
~~Partial - At least 25% of a work week~~
~~Daily Review - Supervisor's review of probationer's daily activities within 24 hours~~

~~Within thirty (30) days of the effective date of this decision, respondent shall have his or her supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number _____ and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.~~

~~If respondent changes employment, it shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his or her new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number _____ and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his or her license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.~~

~~Within ten (10) days of leaving employment, respondent shall notify the board in writing.~~

~~During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the~~

~~board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.~~

~~During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.~~

~~Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.~~

~~Failure to comply with this suspension shall be considered a violation of probation.~~

~~31. No Supervision of Ancillary Personnel~~[2]

~~During the period of probation, respondent shall not supervise any ancillary personnel, including, but not limited to, pharmacy technicians or designated representatives in any entity licensed by the board.~~

~~Failure to comply with this provision shall be considered a violation of probation.~~

32. No Ownership <u>or Management</u> of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, ~~or~~ <u>nor</u> serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

33. Separate File of <u>Controlled Substances</u> Records (~~For~~ ~~pharmacist~~ <u>Pharmacist</u> owners and pharmacists-in-charge)

Respondent shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

34. Report of Controlled Substances (~~For~~ ~~pharmacist~~ <u>Pharmacist</u> owners and

pharmacists-in-charge)

Respondent shall submit ~~quarterly~~ reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board or its designee. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

35. No Access to Controlled Substances

During the period of probation and as directed by the board or its designee, respondent shall not order, possess, dispense or otherwise have access to any controlled substance(s) in Schedules I, II, III, IV or V (Health and Safety Code sections ~~11055~~ 11054 -11058 inclusive). Respondent shall not order, receive or retain any security prescription forms. Failure to comply with this restriction shall be considered a violation of probation.

36. Criminal Probation/Parole Reports

Respondent shall provide a copy of the conditions of any criminal probation/parole to the board, in writing, within ten (10) days of the issuance or modification of those conditions. Respondent shall provide the name of ~~his or her~~ [his/her] probation/parole officer to the board, in writing, within ten (10) days after that officer is designated or a replacement for that officer is designated. Respondent shall provide a copy of all criminal probation/parole reports to the board within ten (10) days after respondent receives a copy of such a report. Failure to timely make any of the submissions required hereby shall be considered a violation of probation.

~~**37. Consultant for Owner or Pharmacist-In-Charge**~~[6]

~~**(Option #1 for pharmacist owners - primarily intended for appropriate cases where the respondent is the sole owner and pharmacist-in-charge of his or her own pharmacy, the standard language should be used in most cases.)**~~

~~During the period of probation, respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge. However, if during the period of probation respondent serves as a pharmacist-in-charge, respondent shall retain an independent consultant at his or her own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the sole owner. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.~~

[6] This term was consolidated in new term 8 – Restrictions on Supervision and Oversight of Licensed Facilitites.

~~**(Option #2 - appropriate for pharmacists who are not pharmacy owners, but who wish, because of their current employment, to remain as the pharmacist-in-charge, and have provided documented mitigating evidence to warrant this option.)**~~

~~During the period of probation, respondent shall not supervise any intern pharmacist, or serve as a consultant to any entity licensed by the board. In the event that the respondent is currently the pharmacist-in-charge of a pharmacy, the pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a [monthly/quarterly] basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval. Within thirty (30) days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy of which he or she is not the current PIC. The board may, in case of an employment change by respondent or for other reasons as deemed appropriate by the board or its designee, preclude the respondent from acting as a pharmacist-in-charge. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.~~

~~**38. Tolling of Suspension**~~

~~During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of the (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.~~

~~Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume the practice of pharmacy until notified by the board that the period of suspension has been satisfactorily completed.~~

~~39~~ 37. Surrender of DEA Permit (Pharmacists and Pharmacist Interns Only)

Within thirty (30) days of the effective date of this decision, respondent shall surrender ~~his or her~~ [his/her] federal Drug Enforcement Administration (DEA) permit to the DEA~~,~~ for cancellation. Respondent shall provide documentary proof of such cancellation to the board or its designee. Respondent is prohibited from ~~prescribing~~ dispensing, furnishing, or otherwise providing dangerous drugs or devices or controlled substances until the board has received satisfactory proof of cancellation. Thereafter, respondent shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option 1: Respondent may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option 2: Respondent shall not order, receive, or retain any federal order forms, including DEA form 222 forms, for controlled substances.

~~40~~ 38. Ethics Course (Pharmacists and Pharmacist Interns Only)

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully ~~and~~ complete it before the end of ~~within~~ the second year of probation, or to timely submit proof of completion to the board or its designee, shall be considered ~~is~~ a violation of probation.

~~Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.~~

39. Facilitated Group Recovery and/or Support Meetings (Appropriate for those cases where the evidence demonstrates substance abuse.)

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a group recovery and/or support meeting that is approved in advance by the board or its designee. The required frequency of group meeting attendance shall be determined by the board or its designee.

The facilitator shall, upon request by the board or its designee, provide the board with a dated document signed by the facilitator that includes respondent's name, the group's name, if any, the date and time of its regular meeting(s), respondent's attendance record, and respondent's participation level and progress. Respondent shall provide signed and dated documentation of attendance as required with each quarterly report. Failure to attend as required or to submit documentation of attendance shall be considered a violation of probation.

40. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
(Appropriate for those cases where the evidence demonstrates substance use.)

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

41. Work Site Monitor (Appropriate for those cases where the evidence demonstrates substance use.)[7]

[7] This probationary term is not new, but is being moved from the previous section "Pharmacy Technician – Standard Terms and Conditions" for purposes of consolidation. The language of this term is also changing from the previous version.

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board or its designee, who shall be responsible for supervising respondent during working hours. Respondent shall provide the proposed work site monitor with a copy of the disciplinary order. Upon approval of the proposed worksite monitor, the respondent shall ensure that the work site monitor signs an affirmation that the work site monitor has reviewed the terms of the disciplinary order and agrees to monitor the respondent as specified by the board. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board monthly or on another schedule as directed by the board or its designee. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the board immediately.

The initial notification shall be made orally within one (1) business day of the occurrence, and shall be followed by written notification within 48 hours of the occurrence. If, for any reason, including change of employment, respondent is no longer able to be monitored by the approved work site monitor within ten (10) days respondent shall designate a new work site monitor for approval by the board or its designee. Failure to timely identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the board by the monitor, shall be considered a violation of probation.

The written reports submitted to the board or its designee by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the board to allow the board or its designee to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

Option for respondents enrolled in PRP or who are given the PRP enrollment term: It is a condition of respondent's enrollment in the Pharmacists Recovery Program (PRP) that [he/she] is required to have a work site monitor approved by the PRP who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the PRP monthly or on another schedule as directed by the PRP. Should the designated work site monitor suspect at any time during the probationary period that respondent has abused alcohol or drugs, he or she shall notify the PRP immediately. The initial notification shall be made orally within one (1) business day of the occurrence, and shall be followed by written notification within two (2) business days of the occurrence. If, for any reason, including change of employment, respondent is not longer able to be monitored by the approved work site monitor, within ten (10) days of commencing new employment for prior approval by the PRP. Failure to identify an acceptable initial or replacement work site monitor, or to ensure monthly reports are submitted to the PRP by the work site monitor, shall be considered a violation of probation.

The written reports submitted to the PRP by the work site monitor shall include at least the following information: respondent's name and license number; the monitor's name, license number (if applicable) and work site location; the date(s) the monitor had face-to-face contact with respondent; the staff interviewed, if applicable; an attendance report; notes on any changes

in respondent's behavior or personal habits; notes on any indicators that may lead to substance abuse; and the work site monitor's signature.

Respondent shall complete any required consent forms and sign any required agreement with the work site monitor and/or the PRP to allow the PRP to communicate freely on the subject of respondent's work performance and sobriety with the work site monitor.

42. Specialized Treatment (Appropriate for those cases where the evidence demonstrates substance abuse.)

Respondent shall comply with all treatment recommendations specified by the clinical evaluation completed pursuant to term 20. If the evaluation indicates enrollment in an inpatient, outpatient or other type of treatment is necessary, respondent shall provide to the board for prior approval the name of the program and the parameters for treatment. Respondent shall provide the program with a copy of the accusation and decision and must complete a consent form authorizing the board to speak with the program about the treatment provided, clinical diagnosis and progress. The board will also receive a discharge summary if appropriate.

The respondent is suspended from work until advised by the board that the suspension is lifted.

PHARMACY TECHNICIAN

The board files cases against pharmacy technicians where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to the following violation(s) of law(s) involving:

- Possession of dangerous drugs and/or controlled substances
- Use of dangerous drugs and/or controlled substances
- Possession for sale of dangerous drugs and/or controlled substances
- Personal misuse of drugs or alcohol

If revocation is not imposed, the board recommends a minimum Category III level of discipline be imposed on the pharmacy technician. This would include suspension and probation.

In addition, a pharmacy technician would be required to obtain certification as defined by Business and Professions Code section 4202(a)(4) prior to resuming work as a pharmacy technician. The board believes that certification prior to resuming work is always warranted in cases where a pharmacy technician license is disciplined but not revoked.

Pharmacy technicians are issued a license based on minimal education, training requirements or certification. No examination is required for issuance of the registration. Pharmacy technicians are not independent practitioners and must work under the supervision of a pharmacist. To place a pharmacy technician on probation places an additional burden on the pharmacist (who may or may not be on probation) to ensure that the respondent pharmacy technician complies with the terms and conditions of his or her probation.

TERMS OF PROBATION – PHARMACY TECHNICIAN[4]

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES

CATEGORY III - Penalty

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.

Maximum: Revocation

Applies to all applicable statutes and regulations

MODEL DISCIPLINARY LANGUAGE – PHARMACY TECHNICIAN[8]

The following standardized language shall be used in every decision where the order of condition is imposed.

Revocation

Pharmacy technician license number _____, issued to respondent _____ is revoked. Respondent shall relinquish his or her technician license to the board within ten (10) days of the effective date of this decision. Respondent may not reapply or petition the board for reinstatement of his or her revoked technician license for three (3) years from the effective date of this decision.

A condition of reinstatement shall be that the respondent is certified as defined in Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board.

Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Option: As a condition precedent to reinstatement of his or her revoked technician license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reapplication or reinstatement of his or her revoked technician license, unless otherwise ordered by the board.

Suspension

As part of probation, respondent is suspended from working as a pharmacy technician for _____ beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have

[8] All information specific to Pharmacy Technician is being removed and consolidated into Terms of Probation – Individual Licensees.

access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

Standard Stay/Probation Order

Pharmacy technician license number _____ is revoked; however the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent surrenders pharmacy technician license number _____ as of the effective date of this decision. Respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not apply for any license, permit, or registration from the board for three (3) years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board, including, but not limited to certification by a nationally recognized body prior to the issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against pharmacy technician license, _____. Respondent is required to report this reprimand as a disciplinary action.

Adoption of Stipulation

It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.

STANDARD CONDITIONS – To be included in all probation decisions/orders.

1. Certification Prior to Resuming Work
2. Obey All Laws
3. Report to the Board
4. Interview with the Board
5. Cooperate with Board Staff
6. Notice to Employers
7. Reimbursement of Board Costs
8. Probation Monitoring Costs
9. Status of License
10. License Surrender While on Probation/Suspension
11. Notification of a Change in Name, Residence Address, Mailing Address or Employment
12. Tolling of Probation
13. Violation of Probation
14. Completion of Probation

OPTIONAL CONDITIONS

15. No Ownership of Licensed Premises
16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
17. Random Drug Screening
18. Work Site Monitor
19. Notification of Departure
20. Abstain from Drugs and Alcohol Use
21. Tolling of Suspension
22. Restitution

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Certification Prior to Resuming Work

Respondent shall be automatically suspended from working as a pharmacy technician until he or she is certified as defined by Business and Professions Code section 4202(a)(4) and provides satisfactory proof of certification to the board. Respondent shall not resume working as a pharmacy technician until notified by the board. Failure to achieve certification within one (1) year shall be considered a violation of probation. Respondent shall not resume working as a pharmacy technician until notified by the board.

During suspension, respondent shall not enter any pharmacy area or any portion of any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises by the board in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

2. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

3. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports

in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

4. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear at two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, pharmacist-in-charge and owner at every pharmacy of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each pharmacy. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician or in any position for which a pharmacy technician license is a requirement or criterion for employment, whether the respondent is considered an employee, independent contractor or volunteer.

7. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

8. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. Status of License

Respondent shall, at all times while on probation, maintain an active, current pharmacy technician license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's pharmacy technician license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her pharmacy technician license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pharmacy technician license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all

requirements applicable to the license sought as of the date the application for that license is submitted to the board.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacy technician in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease working as a pharmacy technician for a minimum of _____ hours per calendar month in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of the work. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

> "Cessation of work" means calendar month during which respondent is not working for at least _____ hours as a pharmacy technician, as defined in Business and Professions Code section 4115. "Resumption of work" means any calendar month during which respondent is working as a pharmacy technician for at least _____ hours as a pharmacy technician as defined by Business and Professions Code section 4115.

13. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a

violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

14. Completion of Probation

Upon written notice by the board indicating successful completion of probation, respondent's pharmacy technician license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

15. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective of this decision. Violation of this restriction shall be considered a violation of probation.

16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

17. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be

determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result in the automatic suspension of work by respondent. Respondent may not resume work as a pharmacy technician until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of or any other board licensed premises (wholesaler, veterinary food-animal drug retailer or any other distributor of drugs) any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the board. Respondent shall not have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect of the practice of pharmacy. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

18. Work Site Monitor (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

19. Notification of Departure (Appropriate for those cases with chemical dependency (alcohol, drugs))

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

20. Abstain from Drugs and Alcohol Use (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

21. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not return to work until notified by the board that the period of suspension has been satisfactorily completed.

22. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

~~DESIGNATED REPRESENTATIVE~~

~~The board files cases against designated representatives where the violation(s) involve significant misconduct on the part of the licensee. The board believes that revocation is typically the appropriate penalty when grounds for discipline are found to exist. Grounds for discipline include, but are not limited to, the following violation(s) of law(s) involving:~~

- ~~Possession of dangerous drugs and/or controlled substances~~
- ~~Use of dangerous drugs and/or controlled substances~~
- ~~Possession for sale of dangerous drugs and/or controlled substances~~
- ~~Personal misuse of drugs or alcohol~~

~~If revocation is not imposed, the board recommends a minimum Category III level of discipline be imposed on the designated representative. This would include suspension and probation.~~

~~TERMS OF PROBATION – DESIGNATED REPRESENTATIVE~~[9]

~~A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of controlled substances is involved. Terms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.~~

~~Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).~~

~~The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.~~

~~CATEGORY OF VIOLATIONS AND RECOMMENDED PENALTIES~~

~~CATEGORY III - Penalty~~

~~Minimum: Revocation; Revocation stayed, 90 days actual suspension, three years probation. All standard terms and conditions shall be included and optional terms and conditions as appropriate.~~

~~Maximum: Revocation~~

~~Applies to all applicable statutes and regulations~~

[9] All information specific to Designated Representative is being removed and consolidated into Terms of Probation – Individual Licensees.

MODEL DISCIPLINARY LANGUAGE – DESIGNATED REPRESENTATIVE

The following standardized language shall be used in every decision where the order of condition is imposed.

Revocation

Designated Representative license number _____, issued to respondent _____ is revoked. Respondent shall relinquish his or her designated representative license to the board within ten (10) days of the effective date of this decision. Respondent may not petition the board for reinstatement of his or her revoked designated representative license for three (3) years from the effective date of this decision.

Respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____ within fifteen (15) days of the effective date of this decision.

Option: As a condition precedent to reinstatement of his or her revoked designated representative license respondent shall reimburse the board for its costs of investigation and prosecution in the amount of $_____. Said amount shall be paid in full prior to the reinstatement of his or her revoked designated representative license, unless otherwise ordered by the board.

Suspension

As part of probation, respondent is suspended from working as a designated representative for _____ beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

Standard Stay/Probation Order

Designated representative license number _____ is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent surrenders designated representative license number _____ as of the effective date of this decision. Respondent shall relinquish his or her designated representative license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent understands and agrees that if he or she ever files an application for licensure or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent may not apply for any license, permit or registration from the board for three (3) years from the effective date of this decision. Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board prior to issuance of a new license. Respondent is required to report this surrender as disciplinary action.

Respondent further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent stipulates that should he or she apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against designated representative license, _____. Respondent is required to report this reprimand as a disciplinary action.

~~Adoption of Stipulation~~

~~It is understood by respondent that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Office of the Attorney General. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

STANDARD CONDITIONS – To be included in all probation decisions/orders.

1. Obey All Laws
2. Report to the Board
3. Interview with the Board
4. Cooperate with Board Staff
5. Notice to Employers
6. No Being Designated Representative-in-Charge
7. Reimbursement of Board Costs
8. Probation Monitoring Costs
9. Status of License
10. License Surrender While on Probation/Suspension
11. Notification of a Change in Name, Residence Address, Mailing Address or Employment
12. Tolling of Probation
13. Violation of Probation
14. Completion of Probation

OPTIONAL CONDITIONS

15. No Ownership of Licensed Premises
16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups
17. Random Drug Screening
18. Work Site Monitor
19. Notification of Departure
20. Abstain from Drugs and Alcohol Use
21. Tolling of Suspension
22. Restitution

STANDARD CONDITIONS - TO BE INCLUDED IN ALL PROBATIONS

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- an arrest or issuance of a criminal complaint for violation of any state or federal law
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, upon request at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his or her probation. Failure to cooperate shall be considered a violation of probation.

5. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number _____ and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his or her direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number _____ and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his or her direct supervisor, designated representative-in-charge and owner at each entity licensed by the board of the terms and conditions of the decision in case number _____ in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his or her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he or she has read the decision in case number _____ and the terms and conditions imposed thereby. It shall be the respondent's responsibility to ensure that his or her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

> "Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a designated representative or in any position for which a designated representative license is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor or volunteer.

6. No Being Designated Representative-in-Charge

During the period of probation, respondent shall not be the designated representative-in-charge of any entity licensed by the board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

7. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his or her responsibility to reimburse the board its costs of investigation and prosecution.

8. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. Status of License

Respondent shall, at all times while on probation, maintain an active, current designated representative license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's designated representative license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her designated representative license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her designated representative license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and the address of the new employer, supervisor and owner and work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

12. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a designated representative in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease working as a designated representative for a minimum of _____ hours in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of work. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

> "Cessation of work" means any calendar month during which respondent is not working as a designated representative for at least _____ hours as a designated representative as defined by Business and Professions Code section 4053.
> "Resumption of work" means any calendar month during which respondent is working as a designated representative for at least _____ hours as a designated representative as defined by Business and Professions Code section 4053.

13. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

14. Completion of Probation

Upon written notice by the board indicating successful completion of probation, respondent's designated representative license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

15. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Option: Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within thirty (30) days of the effective date of this decision, respondent shall begin regular attendance at a recognized and established substance abuse recovery support group in California, (e.g., Alcoholics Anonymous, Narcotics Anonymous, etc.) which has been approved by the board or its designee. Respondent must attend at least one group meeting per week unless otherwise directed by the board or its designee. Respondent shall continue regular attendance and submit signed and dated documentation confirming attendance with each quarterly report for the duration of probation. Failure to attend or submit documentation thereof shall be considered a violation of probation.

17. Random Drug Screening (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent, at his or her own expense, shall participate in random testing, including but not limited to biological fluid testing (urine, blood), breathalyzer, hair follicle testing, or other drug screening program as directed by the board or its designee. Respondent may be required to participate in testing for the entire probation period and the frequency of testing will be determined by the board or its designee. At all times respondent shall fully cooperate with the board or its designee, and shall, when directed, submit to such tests and samples for the detection of alcohol, narcotics, hypnotics, dangerous drugs or other controlled substances as the board or its designee may direct. Failure to timely submit to testing as directed shall be considered a violation of probation. Upon request of the board or its designee, respondent shall provide documentation from a licensed practitioner that the prescription for a detected drug was legitimately issued and is a necessary part of the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Any confirmed positive test for alcohol or for any drug not lawfully prescribed by a licensed practitioner as part of a documented medical treatment shall be considered a violation of probation and shall result

in the automatic suspension of work by respondent. Respondent may not resume work as a designated representative until notified by the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

18. Work Site Monitor (Appropriate for those cases with chemical dependency (alcohol, drugs))

Within ten (10) days of the effective date of this decision, respondent shall identify a work site monitor, for prior approval by the board, who shall be responsible for supervising respondent during working hours. Respondent shall be responsible for ensuring that the work site monitor reports in writing to the board quarterly. Should the designated work site monitor determine at any time during the probationary period that respondent has not maintained sobriety, he or she shall notify the board immediately, either orally or in writing as directed. Should respondent change employment, a new work site monitor must be designated, for prior approval by the board, within ten (10) days of commencing new employment. Failure to identify an acceptable initial or replacement work site monitor, or to ensure quarterly reports are submitted to the board, shall be considered a violation of probation.

19. Notification of Departure (Appropriate for those cases with chemical dependency (alcohol, drugs))

Prior to leaving the probationary geographic area designated by the board or its designee for a period greater than twenty-four (24) hours, respondent shall notify the board verbally and in writing of the dates of departure and return. Failure to comply with this provision shall be considered a violation of probation.

20. Abstain from Drugs and Alcohol Use (Appropriate for those cases with chemical dependency (alcohol, drugs))

Respondent shall completely abstain from the possession or use of alcohol, controlled substances, dangerous drugs and their associated paraphernalia except when the drugs are lawfully prescribed by a licensed practitioner as part of a documented medical treatment. Upon request of the board or its designee, respondent shall provide documentation from the licensed practitioner that the prescription for the drug was legitimately issued and is a necessary part of

the treatment of the respondent. Failure to timely provide such documentation shall be considered a violation of probation. Respondent shall ensure that he or she is not in the same physical location as individuals who are using illicit substances even if respondent is not personally ingesting the drugs. Any possession or use of alcohol, controlled substances, or their associated paraphernalia not supported by the documentation timely provided, and/or any physical proximity to persons using illicit substances, shall be considered a violation of probation.

21. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during suspension shall be considered a violation of probation. Moreover, any absence from California during the period of suspension exceeding ten (10) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within ten (10) days of departure, and must further notify the board in writing within ten (10) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume work until notified by the board that the period of suspension has been satisfactorily completed.

22. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

TERMS OF PROBATION – PREMISES

A minimum three-year probation period has been established by the board as appropriate in most cases where probation is imposed. A minimum five-year probation period has been established by the board as appropriate where self-administration or diversion of dangerous drugs or devices or controlled substances has occurred at a licensed premises. Terms and conditions are imposed to provide consumer protection. A suspension period may also be required as part of the probation order. The board prefers that any stayed order be for revocation rather than for some period of suspension.

Probation conditions are divided into two categories: (1) standard conditions that shall appear in all probation cases, and (2) optional conditions that depend on the nature and circumstances of a particular case. These conditions may vary depending on the nature of the offense(s).

The board may also impose any other condition appropriate to the case where the condition is not contrary to public policy.

CATEGORIES OF VIOLATIONS AND RECOMMENDED PENALTIES

The California Pharmacy Law identifies offenses for which the board may take disciplinary action against a license. Included among grounds for discipline are violations of the Pharmacy Law itself, violations of regulations promulgated by the board, and violations of other state or federal statutes or regulations.

~~The following are categories of possible violations used by the board to determine appropriate disciplinary penalties. These categories represent the judgment of the board as to the perceived seriousness of particular offenses.~~

For those licenses issued to premises (pharmacies and wholesalers, resident and nonresident), the board has identified four (4) categories of violations and associated recommended minimum and maximum penalties for each. These categories of violations are arranged in ascending order from the relatively minor (Category I) to the most serious (Category IV), although any violation in any category, or any combination of violation(s) in one or more categories, may merit revocation.

~~Under each category, the board has grouped statutes and regulations where violations would typically merit the recommended range of minimum to maximum penalties for that category. These lists are representative, and are not intended to be comprehensive or exclusive.~~ For each violation category, the board has given offense descriptions and examples where violations would typically merit the recommended range of minimum to maximum penalties for that category. These descriptions and examples are representative, and are not intended to be comprehensive or exclusive. Where a violation not included in these lists is a basis for disciplinary action, the appropriate penalty for that violation may be best derived by comparison to any analogous violation(s) that are included. Where no such analogous violation is listed, the category descriptions may be consulted.

These categories assume a single violation ~~of each listed statute or regulation~~. For multiple violations, the appropriate penalty shall increase accordingly. Moreover, if an individual has committed violations in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.

The board also has the authority, pursuant to Business and Professions Code section 4301(n), to impose discipline based on disciplinary action taken by another jurisdiction. The discipline imposed by the board will depend on the discipline imposed by the other jurisdiction, the extent of the respondent's compliance with the terms of that discipline, the nature of the conduct for which the discipline was imposed, and other factors set forth in these guidelines.

CATEGORY I

Minimum: Revocation; Revocation stayed; one-year probation. All standard terms and conditions shall be included and may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category I discipline is recommended for violations which are relatively minor but are potentially harmful:

- violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- smaller or isolated failure(s) to abide by or enforce prescription or refill requirements, drug-substitution requirements, or labeling requirements;
- violation(s) of obligations to supply or update information to the board, or to other enforcement or regulatory agencies;
- failure(s) to adequately supervise staff to ensure security and sanitation of premises, dangerous drugs or devices or controlled substances;
- violation(s) of packaging requirements, security control requirements, or reporting requirements; and
- failure(s) to display original license(s), or to supply name(s) of owner(s), manager(s), or employee(s).
- ~~violations which are relatively minor but are potentially harmful~~
- ~~repeated violations of a relatively minor nature~~

~~Violations of the following codes are representative of this category:~~

~~**BUSINESS AND PROFESSIONS CODE**~~

~~**Article 3. Scope of Practice and Exemptions**~~

~~4053 Exemptee Supervisor of Manufacturer, etc.: Requirements~~
~~4054 Supply by Manufacturer, etc. of Certain Dialysis Drugs and Devices~~
~~4056 Purchase of Drugs at Wholesale – Hospital Containing 100 Beds or Less~~
~~4057 Exceptions to Application of this Chapter~~
~~4058 Display of Original License~~
~~4062 Furnishing Dangerous Drugs During Emergency~~
~~4064 Emergency Refill of Prescription Without Prescriber Authorization~~
~~4065 Injection Card System; Requirements for Administration~~
~~4066 Furnishing Dangerous Drugs to Master or First Officer of Vessel~~

~~Article 4. Requirements for Prescription~~

~~4070 Reduction of Oral or Electronic Prescription to Writing~~
~~4071 Prescriber May Authorize Agent to Transmit Prescription; Schedule II Excluded~~
~~4072 Oral or Electronic Transmission of Prescription - Health Care Facility~~
~~4073 Substitution of Generic Drug - Requirements and Exceptions~~
~~4074 Drug Risk: Informing Patient; Providing Consultation for Discharge Medications~~
~~4076 Prescription Container - Requirements for Labeling~~
~~4077 Dispensing Dangerous Drug in Incorrectly Labeled Container~~

~~Article 5. Authority of Inspectors~~

~~4082 Names of Owners, Managers and Employees Open for Inspection~~

~~Article 6. General Requirements~~

~~4100 Change of Address or Name—Notification to Board~~
~~4103 Blood Pressure - Taking by Pharmacist~~

~~Article 7. Pharmacies~~

~~4114 Intern Pharmacist: Activities Permitted~~
~~4119.5 Transfer or Repackaging Dangerous Drugs by Pharmacy~~
~~4120 Nonresident Pharmacy: Registration Required~~
~~4121 Advertisement for Prescription Drug: Requirements; Restrictions~~
~~4122 Required Notice at Availability of Prescription Price Information, General Product Availability, Pharmacy Services; Providing Drug Price Information; Limitations on Price Information Requests~~
~~4123 Compounding Drug for Other Pharmacy for Parenteral Therapy; Notice to Board~~
~~4124 Dispensing Replacement Contact Lenses: Requirements; Patient Warnings; Registration with Medical Board; Application of Section to Nonresident Pharmacies~~

~~Article 9. Hypodermic Needles and Syringes~~

~~4141 Furnishing Without License~~
~~4142 Prescription Required~~
~~4143 Exemption: Sale to Other Entity, Physician, etc.~~
~~4144 Industrial Use Exception~~
~~4145 Exception: Furnishing for Administration of Insulin, Adrenaline, or Specified Animal Uses; Conditions~~
~~4148 Confiscation if Found Outside Licensed Premises~~
~~4149 Sale by Distributor~~

~~Article 10. Pharmacy Corporations~~

~~4151 Licensure Requirements~~
~~4152 Corporate Name Requirements~~
~~4153 Shareholder Income While Disqualified~~
~~4156 Unprofessional Conduct by Corporation~~

~~Article 11. Wholesalers and Manufacturers~~

~~4161 Nonresident Wholesaler: When License Required; Application~~
~~4162 Issuance or Renewal of Wholesaler License; Surety Bond~~
~~4164 Reports Required~~
~~4165 Sale or Transfer of Dangerous Drug or Device Into State: Furnishing Records to Authorized Officer on Demand; Citation for Non-compliance~~
~~4166 Shipping of Dangerous Drugs or Devices -- Wholesaler or Distributor~~
~~4167 Wholesaler: Bar on Obtaining Dangerous Drugs or Devices It Cannot Maintain on Licensed Premises~~

~~Article 13. Non-Profit or Free Clinics~~

~~4180 Purchase of Drugs at Wholesale Only with License: Eligible Clinics~~
~~4181 License Requirements; Policies and Procedures; Who May Dispense~~
~~4182 Duties of Professional Director; Consulting Pharmacist Required~~
~~4183 No Professional Dispensing Fee~~
~~4184 Dispensing Schedule II Substance Prohibited~~
~~4186 Automated Drug Delivery Systems~~

~~Article 14. Surgical Clinics~~

~~4190 Purchase of Drugs at Wholesale: Permitted Uses of Drugs; Required Records and Policies; License Required~~
~~4191 Compliance with Department of Health Services Requirements; Who May Dispense Drugs~~
~~4192 Duties of Professional Director; Providing Information to Board~~
~~4193 Clinic Not Eligible for Professional Dispensing Fee; Ban on Offering Drugs for Sale~~
~~4194 Dispensing of Schedule II Substance by Clinic Prohibited; Physician May Dispense; Administration Authorized in Clinic~~

~~Article 15. Veterinary Food-Animal Drug Retailers~~

~~4196 License Required: Temporary License on Transfer of Ownership; Persons Authorized in Storage Area~~
~~4197 Minimum Standards: Security; Sanitation; Board Regulations; Waivers~~
~~4198 Written Policies and Procedures Required: Contents; Training of Personnel; Quality Assurance; Consulting Pharmacist~~

~~Article 17. Continuing Education~~

~~4231 Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee~~
~~4232 Content of Courses~~

~~Article 18. Poisons~~

~~4240 Application of Act~~

~~Article 20. Prohibitions and Offenses~~

4341 Advertisement of Prescription Drugs or Devices
4343 Buildings: Prohibition Against Use of Certain Signs Unless Licensed Pharmacy Within

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1704 Change of Address
1705 Notification of Bankruptcy, Receivership or Liquidation
1708.2 Discontinuance of Business
1708.4 Pharmacist Handling Radioactive Drugs
1708.5 Pharmacy Furnishing Radioactive Drugs
1709 Names of Owners and Pharmacist in Charge
1714 Operational Standards and Security
1715.6 Reporting Drug Loss
1716 Variation from Prescriptions
1717 Pharmaceutical Practice
1717.1 Common Electronic Files
1717.4 Electronic Transmission of Prescriptions
1718.1 Manufacturer's Expiration Date
1726 Supervision of Intern Pharmacists
1728 Requirements for Examination
1732.1 Requirements for Accredited Providers
1732.3 Requirements for Continuing Education Courses
1732.4 Provider Audit Requirements
1732.5 Renewal Requirements for Pharmacist
1744 Drug Warnings
1751 Sterile Injectable Compounding Area
1751.01 Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients
1751.02 Policies and Procedures
1751.11 Furnishing to Home Health Agencies and Licensed Hospices
1751.12 Obligations of a Pharmacy Furnishing Portable Containers
1771 Posting of Notice of Suspension
1772 Disciplinary Condition of Suspension
1780 Minimum Standards for Wholesalers
1780.1 Minimum Standards for Veterinary Food-Animal Drug Retailers
1781 Exemption Certificate
1786 Exemptions
1787 Authorization to Distribute Hemodialysis Drugs and Devices
1790 Assembling and Packaging
1791 Labeling
1792 Receipt for Shipment

HEALTH AND SAFETY CODE

11100 Report of Certain Chemical: Chemicals Included; Exclusions; Penalties
11100.1 Report of Chemicals Received from Outside State; Penalties
11151 Limitation on Filling Prescriptions From Medical Students

~~11158 Prescription Required for Schedule II, III, IV, or V Controlled Substance; Exception for Limited Dispensing, Administration~~
~~11159 Chart Order Exemption for Patient in County or Licensed Hospital; Maintaining Record for Seven Years~~
~~11159.1 Chart Order Exemption for Clinic Patient; Maintaining Record for Seven Years~~
~~11159.2 Exception to Triplicate Prescription Requirement~~
~~11167 Emergency Dispensing of Schedule II Substance: Circumstances and Requirements~~
~~11167.5 Oral or Electronic Prescriptions for Schedule II Controlled Substance for Specified Inpatients, Residents, and Home Hospice Patients; Requirements~~
~~11171 Prescribing, etc. Controlled Substance Only as Authorized~~
~~11172 Antedating or Postdating Prescription Prohibited~~
~~11175 Prohibition on Obtaining or Possessing Nonconforming Prescription; Prohibition on Obtaining Controlled Substance by Nonconforming Prescription~~
~~11180 Prohibition on Controlled Substance Obtained or Possessed by Nonconforming Prescription~~
~~11200 Restrictions on Dispensing or Refilling; Refill of Schedule II Prescription Barred~~
~~11201 Emergency Refill of Schedule III, IV, or V Prescription; Circumstances; Requirements~~
~~11205 Maintenance and Retention of Records in Separate File~~
~~11206 Required Information on Prescription~~
~~11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation~~
~~11210 Issuing Prescription: By Whom; For What Purpose; Quantity to Be Prescribed~~
~~11250 Authorized Retail Sale by Pharmacists to Physicians, etc.; Required Order Form~~
~~11251 Authorized Wholesale Sale by Pharmacists~~
~~11252 Preservation of Federally Required Forms~~
~~11253 Duration of Retention~~
~~11255 Actions Constituting Sale~~
~~11256 Required Report of Order By or Sale to Out-of-State Wholesaler or Manufacturer~~
~~111225 to~~
~~111655 Adulterated or Misbranded Drugs or Devices~~

~~CODE OF FEDERAL REGULATIONS, TITLE 21~~

~~1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.~~
~~1301.14 Filing of application; acceptance for filing; defective applications.~~
~~1301.71 Security requirements generally.~~
~~1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.~~
~~1301.73 Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.~~
~~1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.~~
~~1301.77 Security controls for freight forwarding facilities.~~
~~1301.90 Employee screening procedures.~~
~~1301.91 Employee responsibility to report drug diversion.~~
~~1301.92 Illicit activities by employees.~~
~~1302.03 Symbol required; exceptions.~~

~~1302.04 Location and size of symbol on label and labeling.~~
~~1302.05 Effective dates of labeling requirements.~~
~~1302.06 Sealing of controlled substances.~~
~~1302.07 Labeling and packaging requirements for imported and exported substances.~~
~~1304.11 Inventory requirements.~~
~~1304.31 Reports from manufacturers importing narcotic raw material.~~
~~1304.32 Reports of manufacturers importing coca leaves.~~
~~1304.33 Reports to ARCOS.~~
~~1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.~~
~~1305.04 Persons entitled to order Schedule I and II controlled substances.~~
~~1305.05 Power of attorney.~~
~~1305.06 Persons entitled to fill orders for Schedule I and II controlled substances.~~
~~1305.11 Procedure for obtaining DEA Forms 222.~~
~~1305.12 Procedure for executing DEA Forms 222.~~
~~1305.14 Procedure for endorsing DEA Forms 222.~~
~~1305.15 Unaccepted and defective DEA Forms 222.~~
~~1305.16 Lost and stolen DEA Forms 222.~~
~~1306.03 Persons entitled to issue prescriptions.~~
~~1306.05 Manner of issuance of prescriptions.~~
~~1306.14 Labeling of substances and filling of prescriptions.~~
~~1306.24 Labeling of substances and filing of prescriptions.~~
~~1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.~~
~~1306.26 Dispensing without a prescription.~~
~~1307.11 Distribution by dispenser to another practitioner or reverse distributor.~~
~~1307.12 Distribution to supplier or manufacturer.~~
~~1307.13 Incidental manufacture of controlled substances.~~
~~1307.21 Procedure for disposing of controlled substances.~~
~~1700.1 to~~
~~1707.15 Child-resistant containers.~~

CATEGORY II

Minimum: Revocation; Revocation stayed, three years probation (five years probation where self-administration or diversion of dangerous drugs or devices or controlled substances occurred at the licensed premises). All standard terms and conditions shall be included and may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category II discipline is recommended for violations with serious potential for harm, as well as for violations involving disregard for public safety or for laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or devices or controlled substances, violations that reflect on ethics, competency, or diligence, and criminal convictions not involving alcohol, dangerous drugs or devices or controlled substances. Violations in this category may include:

- failure(s) to abide by prohibitions on referral rebates or discounts (kickbacks) and/or volume or percentage-based lease agreements;

- violation(s) of advertising or marketing limitations, including use of false or misleading advertising or marketing;
- repeat or serious violation(s) of recordkeeping requirements, scope of practice requirements, or inventory control requirements;
- violation(s) of controlled substance secure prescription requirements, inventory controls, or security requirements;
- failure(s) to meet compliance requirements, including pharmacist-in-charge or designated representative-in-charge designation and duties;
- violation(s) of monitoring and reporting requirements with regard to chemically, mentally, or physically impaired licensees or employees;
- repeat or serious failure(s) to adequately supervise staff or ensure security and sanitation of premises, dangerous drugs or devices or controlled substances;
- violation(s) of laws governing dangerous drugs or devices and controlled substances, including smaller cases of diversion or self-administration;
- unlawful possession(s) of dangerous drugs or devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- smaller scale dispensing or furnishing of dangerous drugs or devices via the internet, without valid a prescription;
- purchasing, trading, selling, or transferring dangerous drugs or devises to or from unauthorized person(s);
- failure(s) to make required reports to the board or to other regulatory agencies, including CURES obligations and reporting to the DEA;
- violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs or devices or controlled substances;
- repeat or serious deviation(s) from the requirements of prescription(s) or failure(s) to clarify erroneous or uncertain prescription(s);
- gross immorality, incompetence, gross negligence, clearly excessive furnishing of controlled substances, moral turpitude, dishonestly, or fraud;
- criminal conviction(s) not involving alcohol, dangerous drugs or devices or controlled substances;
- violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- subverting or attempting to subvert an investigation conducted by the board.
- ~~violations with a serious potential for harm~~
- ~~violations which involve greater disregard for pharmacy law and public safety~~
- ~~violations which reflect on ethics, care exercised or competence or a criminal conviction not involving dangerous drugs or controlled substances or involving possession or use of dangerous drugs or controlled substances.~~

~~Violations of the following codes are representative of this category:~~

~~BUSINESS AND PROFESSIONS CODE~~

~~650 Rebates or Discounts for Referral Prohibited~~
~~650.1 Lease Prohibition – Hospitals or Prescribers~~
~~651 Professional Advertising Requirements~~

~~Article 3. Scope of Practice and Exemptions~~

4051(b) Conduct Authorized by Pharmacist
4052 Furnishing to Prescriber; Permissible Procedures by Pharmacist in Health Care Facility or Clinic or for Other Health Care Provider
4060 Controlled Substance – Prescription Required; Exceptions
4061 Distribution of Drug as Sample; Written Request Required
4064 Emergency Refill of Prescription Without Prescriber Authorization
4067 Internet; Dispensing Dangerous Drugs or Devices without Prescription
4075 Proof of Identity Required – Oral or Electronic Prescription
4078 False or Misleading Label on Prescription

Article 6. General Requirements

4101 Pharmacist in Charge, Exemptee: Termination of Employment; Notification to Board
4104 Licensed Employee, Theft or Impairment: Pharmacy Procedures
4105 Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records

Article 7. Pharmacies

4112 Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
4113 Pharmacist in Charge: Notification to Board; Responsibilities
4115 Pharmacy Technician: Activities Permitted; Required Supervision; Activities Limited to Pharmacist; Registration; Requirements for Registration; Ratios
4115.5 Pharmacy Technician Trainee; Placement; Supervision; Requirements
4116 Security of Dangerous Drugs and Devices in Pharmacy: Pharmacist Responsibility for Individuals on Premises; Regulations
4117 Admission to Area Where Narcotics are Stored, etc. – Who May Enter
4120 Nonresident Pharmacy: Registration Required
4125 Pharmacy Quality Assurance Program Required; Records Considered Peer Review Documents

Article 9. Hypodermic Needle and Syringes

4140 Unlawful Possession
4147 Disposal of Needle or Syringe

Article 11. Wholesalers and Manufacturers

4161 Nonresident Wholesaler: When License Required; Application
4163 Unauthorized Furnishing by Manufacturer or Wholesale
4164 Reports Required
4169(a)(1) Prohibited Acts

Article 13. Non-Profit of Free Clinics

4185 Inspection Permitted

Article 14. Surgical Clinics

4195 Inspection Permitted

~~Article 19. Disciplinary Proceedings~~

~~4301 Unprofessional Conduct - subsections (a)-(h), (j), and (l) - (q)~~
~~4302 Discipline of Corporate Licensee for Conduct of Officer, Director, Shareholder~~
~~4303 Nonresident Pharmacy: Grounds for Discipline~~
~~4304 Out-of-state Distributor: Authority to Discipline~~
~~4305 Disciplinary Grounds: Failure of Pharmacy, Pharmacist to Notify Board of Termination of Pharmacist in Charge; Continuing to Operate Without Pharmacist~~
~~4305.5 Disciplinary Grounds: Failure of Other Entity Licensed by Board, of Pharmacist or Exemptee to Notify Board of Termination of Pharmacist in Charge or Exemptee; Continuing to Operate Without Pharmacist or Exemptee~~
~~4306 Violation of Professional Corporation Act as Unprofessional Conduct~~
~~4306.5 Misuse of Education, etc. by Pharmacist Outside Course of Practice of Pharmacy as Unprofessional Conduct~~

~~Article 20. Prohibitions and Offenses~~

~~4326 Misdemeanor: Obtaining Needle or Syringe by Fraud, etc.; Unlawful Use of Needle or Syringe Obtained from Another~~
~~4328 Misdemeanor: Permitting Compounding, Dispensing, or Furnishing by Non-pharmacist~~
~~4330 Misdemeanor: Non-pharmacist Owner Failing to Place Pharmacist in Charge, Dispensing or Compounding Except by Pharmacist, Interfering with Pharmacist in Charge~~
~~4331 Misdemeanor: Medical Device Retailer, Wholesaler, Veterinary Food-Animal Drug Retailer Failing to Place Pharmacist or Exemptee in Charge, Permitting Dispensing or Compounding Except by Pharmacist or Exemptee~~
~~4333 Maintaining Prescriptions, Other Drug Records on Premises, Open to Inspection; Waiver; Willful Failure to Keep or Permit Inspection of Records of Prescriptions, Other Records as Misdemeanor~~
~~4340 Unlawful Advertising by Nonresident Pharmacy Not Registered with Board~~

~~Article 22. Unfair Trade Practices~~

~~4380 Resale of Preferentially Priced Drugs; Prohibition; Exceptions~~
~~4382 Board May Audit Sales to Walk-in Customers~~

~~CALIFORNIA CODE OF REGULATIONS, TITLE 16~~

~~1707.1 Duty to Maintain Medication Profiles (Patient Medication Records)~~
~~1707.2 Notice to Consumers and Duty to Consult~~
~~1707.3 Duty to Review Drug Therapy and Patient Medication Record Prior to Deliver~~
~~1709.1 Designation of Pharmacist in Charge~~
~~1714.1 Pharmacy Operation During Temporary Absence of a Pharmacist~~
~~1715 Self-Assessment of a Pharmacy by the Pharmacist-in-Charge~~
~~1715.5 Implementation of Electronic Monitoring of Schedule II Prescriptions~~
~~1716.1 Compounding Unapproved Drugs for Prescriber Office Use~~
~~1716.2 Record Requirements-Compounding for Future Furnishing~~
~~1717.2 Notice of Electronic Prescription Files~~

1717.3 Preprinted, Multiple Checkoff Prescription Blanks
1723.1 Confidentiality of Examination Questions
1745 Partial Filling of Schedule II Prescriptions
1751.10 Furnishing to Parenteral Patient at Home
1761(a) Erroneous or Uncertain Prescriptions
1764 Unauthorized Disclosure of Prescriptions
1765 Commissions, Gratuities, and Rebates
1766 False or Misleading Advertising
1775.3 Compliance with Orders of Abatement
1782 Reporting Sales of Drugs Subject to Abuse
1783 Manufacturer or Wholesaler Furnishing Drugs or Devices
1793.1 Duties of a Pharmacist
1793.2 Duties of a Pharmacy Technician
1793.3 Other Non-Licensed Pharmacy Personnel
1793.4 Qualifications for Registration as a Pharmacy Technician
1793.7 Requirements for Pharmacies Employing Pharmacy Technicians
1793.8 Technicians in Hospitals with Clinical Pharmacy Programs

HEALTH AND SAFETY CODE

11103 Report of Theft, Loss, or Shipping Discrepancy
11150 Persons Authorized to Write or Issue a Prescription
11152 Nonconforming Prescriptions Prohibited
11154 Prescription, etc. Must Be for Treatment; Knowing Soliciting of Unlawful Prescription, etc.
11156 Prescribing, etc. Controlled Substances to Addict Only as Authorized
11164 Prescriptions for Schedule II, III, IV and V Controlled Substance: Form and Content; Record of Practitioner Dispensing Schedule II Controlled Substance
11165(d) CURES Transmission
11166 Time Limit for Filling Schedule II Prescription; Knowingly Filling Mutilated, Forged, or Altered Prescription Prohibited
11170 Prohibition on Prescribing, etc. Controlled Substance for Self
11179 Retention of Controlled Substance Prescription
11207 Only Pharmacist or Intern Authorized to Fill Prescription
11209 Delivery and Receiving Requirements for Schedule II, III, and IV Substances; Violation
11350 Possession of Specified Controlled Substance
11377 Unlawful Possession of Specified Substance

CODE OF FEDERAL REGULATIONS, TITLE 21

1304.03 Persons required to keep records and file reports.
1304.04 Maintenance of records and inventories.
1304.11 Inventory requirements.
1304.21 General requirements for continuing records.
1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.
1305.07 Special procedures for filling certain orders.
1305.13 Procedure for filling DEA Forms 222.

~~1306.04 Purpose of issue of prescription.~~
~~1306.06 Persons entitled to fill prescriptions.~~
~~1306.11 Requirement prescription.~~
~~1306.12 Refilling prescriptions.~~
~~1306.13 Partial filling of prescriptions.~~
~~1306.21 Requirement of prescription.~~
~~1306.22 Refilling of prescriptions.~~
~~1306.23 Partial filling of prescriptions.~~

CATEGORY III

Minimum: Revocation; Revocation stayed, 90 days actual suspension, three to five years probation (five years probation where self-administration or diversion of dangerous drugs or devices or controlled substances occurred at the licensed premises). All standard terms and conditions shall be included and may include optional terms and conditions, as appropriate.

Maximum: Revocation

Category III discipline is recommended for violations where potential for harm is greater, more imminent, or more serious than it is for Category II violations, as well as for violations that involve knowingly or willfully violating laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or devices or controlled substances, and most criminal convictions involving alcohol, dangerous drugs or controlled substances. Violations in this category may include:

- violation(s) involving creation, manipulation, perpetuation, or disregard of drug shortages;
- failure(s) to deploy or abide by electronic pedigree requirements for dangerous drugs;
- violation(s) of licensee's corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances;
- dispensing or furnishing without valid prescription, dispensing or furnishing to unauthorized person(s);
- violation(s) involving fraudulent acts committed in connection with the licensee's practice;
- repeat or serious unlawful possession(s) of dangerous drugs or dangerous devices, controlled substances, hypodermic needles or syringes, or drug paraphernalia;
- larger scale dispensing or furnishing of dangerous drug(s) or device(s) via the internet, without valid prescription(s);
- purchasing, trading, selling, or transferring adulterated, misbranded, or expired dangerous drug(s) or device(s);
- removal, sale, or disposal of embargoed dangerous drug(s) or device(s);
- failing to maintain record(s) of acquisition and disposition of dangerous drug(s) or devise(s) or controlled substances
- resale(s) of preferentially prices drugs, contract bid diversion, or other instances of improper sale(s) or resale(s);
- repeat or serious violation(s) of quality assurance and self-assessment obligations, failure(s) to ensure properly trained staff and conduct practice safely;
- repeat or serious failure(s) to perform drug utilization reviews, monitor patient medication profiles, or promote safety and efficacy of prescribed drugs;

- forgery of prescriptions, passing of forged prescriptions, or other unlawful means of acquiring dangerous drug(s) or device(s) or controlled substances(s);
- repeat or serious acts violating, assisting in or abetting violation of, or conspiring to violate the laws and regulations governing pharmacy; and
- violation(s) involving providing or offering to provide controlled substance(s) to addict(s).
- ~~most criminal convictions involving dangerous drugs or controlled substances~~
- ~~knowing or willfully violating laws or regulations pertaining to dispensing or distributing dangerous drugs or controlled substances~~
- ~~fraudulent acts committed in connection with the licensee's practice~~
- ~~drug shortages~~
- ~~violation of a licensee's corresponding responsibility.~~

~~Violations of the following codes are representative of this category:~~

~~BUSINESS AND PROFESSIONS CODE~~

~~Article 3. Scope of Practice and Exemptions~~

~~4051(a) Conduct Limited to Pharmacist~~
~~4059 Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions~~
~~4059.5 Who May Order Dangerous Drugs or Devices: Exceptions~~

~~Article 5. Authority of Inspectors~~

~~4080 Stock of Dangerous Drugs and Devices Kept Open for Inspection~~
~~4081 Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory~~
~~4085(a) Unlawful to Remove, Sell, Dispose of Embargoed Dangerous Drug or Dangerous Device~~

~~Article 7. Pharmacies~~

~~4110 License Required; Temporary Permit Upon Transfer of Ownership~~
~~4111 Restrictions on Prescriber Ownership~~

~~Article 11. Wholesalers and Manufacturers~~

~~4169(a)(2) to~~
~~4169(a)(5) Prohibited Acts~~

~~Article 15. Veterinary Food-Animal Retailers~~

~~4199 Labeling Requirements; Maintaining Prescription Records~~

~~Article 19. Disciplinary Proceedings~~

~~4301 Unprofessional Conduct - subsections (i) - (k) and (o)~~
~~4307 Prohibition of Association of Individual with Entity License by Board: Length of Prohibition; Individuals Covered; Imposition of Prohibition Through Administrative Act Proceeding~~

4308 Prohibited Association: Notification of Affected Licensees Known to Board

Article 20. Prohibitions and Offenses

4322 Misdemeanor or Infraction: False Representations to Secure License for Self or Others; False Representation of Licensure; Penalties
4323 Misdemeanor: False Representation of Self as Physician, Agent of Physician, etc. to Obtain Drug
4324 Felony or Misdemeanor: Forgery of Prescription; Possession of Drugs Obtained Through Forged Prescription
4325 Misdemeanor: Manufacture, Possession, etc. of False Prescription Blank
4327 Misdemeanor: Sale, Dispensing, or Compounding While Under the Influence of Drugs or Alcoholic Beverages
4329 Misdemeanor: Non-pharmacist Acting as Manager, Compounding, Dispensing or Furnishing Drugs
4332 Misdemeanor: Failure or Refusal to Maintain or Produce Required Drug or Device Records; Willful Production of False Records
4335 Voided License: Knowing Failure to Arrange for Disposition of Stock as Misdemeanor
4336 Felony: Knowing or Willful Use of Minor to Violate Specified Sections of Pharmacy Law: Exception for Pharmacist Furnishing Pursuant to a Prescription

Article 22. Unfair Trade Practices

4380 Resale of Preferentially Priced Drugs: Prohibition; Exceptions

CALIFORNIA CODE OF REGULATIONS, TITLE 16

1718 Current Inventory Defined
1761(b) Erroneous or Uncertain Prescriptions
1771 Posting of Notice of Suspension
1772 Disciplinary Condition of Suspension
1773 Disciplinary Conditions of Probation of Pharmacist
1774 Disciplinary Conditions of Probation of Permit

HEALTH AND SAFETY CODE

11104 Providing Chemical for Illicit Manufacturing; Evasion of Reporting Requirements; Penalties
11105 False Statement in Report
11150 Persons Authorized to Write or Issue a Prescription
11153 Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist
11153.5 Wholesaler or Manufacturer Furnishing Controlled Substance Other Than for Legitimate Medical Purpose; Knowing Violation; Factors in Assessing Legitimacy
11157 No False or Fictitious Prescriptions
11162.5 Counterfeiting or Possession of Counterfeit Triplicate Prescription Blank; Penalty
11167.5 Pharmacy Generated Prescription for Schedule II Controlled Substance in a Skilled Nursing Facility

~~11173 Fraud, Deceit, Misrepresentation or False Statement; False Representation; False Label~~
~~11174 Prohibition on Providing False Name or Address in Connection with Prescription, etc.~~
~~11351 Possession or Purchase for Sale of Specified Controlled Substance~~
~~11368 Forged or Altered Prescriptions~~
~~11375 Possession for Sale or Selling Specified Substance~~
~~11378 Possession for Sale~~
~~11550 Using or Being Under Influence of Controlled Substance~~
~~111295 Manufacturing, Selling or Offering for Sale an Adulterated Drug or Device~~
~~111300 Unlawful to Adulterate a Drug~~
~~111305 Unlawful to Receive in Commerce an Adulterated Drug~~
~~111440 Unlawful Manufacturer, selling a misbranded Drug~~
~~111445 Unlawful for a Person to Misbrand~~
~~111450 Unlawful to Receive into Commerce a Drug that is Misbranded~~

CATEGORY IV

Penalty: Revocation

Category IV discipline (~~Revocation~~ revocation) is recommended for the most serious violations of ~~the Uniform Controlled Substance Act (Heath and Safety Code 11000 et seq.) involving~~ laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs or devices or controlled substances. Violations in this category may include:

- violation(s) involving possession for sale, transportation, importation, and/or use of a minor for unlawful acquisition of sale, of controlled substances;
- criminal conviction(s) involving the above, or repeat convictions involving diversion or abuse of alcohol, dangerous drugs or devices, or controlled substances; and
- repeat or serious example(s) of conduct described in Category I, Category II, or Category III.
- ~~possession for sale~~
- ~~transportation~~
- ~~importation~~
- ~~sale~~
- ~~use of a minor for the unlawful sale of controlled substances~~

Revocation is also recommended ~~when~~ where a respondent fails to file a notice of defense to an Accusation or to appear at a disciplinary hearing, where a respondent violates the terms and conditions of probation from a previous disciplinary order, or where prior discipline has been imposed on the license.~~:~~

- ~~a respondent fails to file a notice of defense or to appear at a disciplinary hearing where the board has requested revocation in the accusation~~
- ~~a respondent violates the terms and conditions of probation from a previous disciplinary order~~
- ~~prior discipline has been imposed, as progressive discipline unless the respondent can demonstrate satisfactory evidence of rehabilitation.~~

~~Violations of the following codes are representative of this category:~~

~~**HEALTH AND SAFETY CODE**~~

~~11352 Importing, Selling, Furnishing Controlled Substance~~
~~11353 Adult Inducing Minor to Violate Provisions~~
~~11379 Transporting, Importing, Selling Controlled Substance~~
~~11380 Adult Using, Soliciting or Intimidating Minor for Violation~~

MODEL DISCIPLINARY LANGUAGE - PREMISES

The following standardized language shall be used in every decision where the order or condition is imposed.

Revocation

License number _____, issued to respondent _____, is revoked.

Respondent ~~owner~~ shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all dangerous drugs or devices or controlled substances and dangerous drugs and devices. Respondent ~~owner~~ shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five (5) days of disposition.

Option: Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Suspension

License number _____, issued to respondent _____ is suspended for a period of _____ days beginning the effective of this decision.

Respondent shall cease all ~~pharmacy~~ operations as a [insert license type] during the period of suspension. Failure to comply with ~~this~~ any such suspension shall be considered a violation of probation.

Standard Stay/Probation Order

License number _____, issued to respondent is revoked; however, the revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Issuance of Probationary License (In cases where a Statement of Issues has been filed.)

Upon satisfaction of all statutory and regulatory requirements for issuance of a [insert license type] license, a license shall be issued to respondent and immediately revoked; the order of revocation is stayed and respondent is placed on probation for _____ years upon the following terms and conditions:

Surrender

Respondent ~~owner~~ surrenders license number _____ as of the effective date of this decision. Respondent ~~owner~~ shall relinquish the premises wall license and renewal license to the board within ten (10) days of the effective date of this decision.

The surrender of respondent's license and the acceptance of the surrendered license by the board shall constitute the imposition of discipline against respondent. This decision constitutes a record of discipline and shall become a part of respondent's license history with the board.

Respondent ~~owner~~ shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent ~~owner~~ shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent ~~owner~~ understands and agrees that if ~~he or she~~ [he/she] ever files an application for a licensed premises or a petition for reinstatement in the State of California, the board shall treat it as a new application for licensure.

Respondent ~~owner~~ may not reapply for any license from the board for three (3) years from the effective date of this decision. Respondent ~~owner~~ stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision, all allegations set forth in the [accusation or petition to revoke probation] shall be deemed to be true, correct and admitted by respondent when the board determines whether to grant or deny the application. Respondent shall satisfy all requirements applicable to that license as of the date the application is submitted to the board. Respondent is required to report this surrender as disciplinary action.

Respondent ~~owner~~ further stipulates that ~~he or she~~ [he/she] shall reimburse the board for its costs of investigation and prosecution in the amount of $_____ within _____ days of the effective date of this decision.

Option: Respondent ~~owner~~ stipulates that should ~~he or she~~ [he/she] apply for any license from the board on or after the effective date of this decision the investigation and prosecution costs in the amount of $_____ shall be paid to the board prior to issuance of the new license.

Public Reprimand

It is hereby ordered that a public reprimand be issued against licensee, _____. Respondent ~~owner~~ is required to report this reprimand as a disciplinary action.

~~**Adoption of Stipulation**~~

~~It is understood by respondent owner that, in deciding whether to adopt this stipulation, the board may receive oral and written communication from its staff and the Attorney General's Office. Communications pursuant to this paragraph shall not disqualify the board or other persons from future participation in this or any other matter affecting respondent. In the event this settlement is not adopted by the board, the stipulation will not become effective and may not be used for any purpose, except this paragraph, which shall remain in effect.~~

STANDARD CONDITIONS - To be included in all probation decisions/orders.

1. Definition: Respondent
~~1~~ 2. Obey All laws
~~2~~ 3. Report to the Board
~~3~~ 4. Interview with the Board
~~4~~ 5. Cooperate with Board Staff
~~5~~ 6. Reimbursement of Board Costs
~~6~~ 7. Probation Monitoring Costs
~~7~~ 8. Status of License
~~8~~ 9. License Surrender While on Probation/Suspension
10. Sale or Discontinuance of Business
~~9~~ 11. Notice to Employees
~~10~~ 12. Owners and Officers: Knowledge of the Law
13. Premises Open for Business
~~11~~ 14. Posted Notice of Probation
~~12~~ 15. Violation of Probation
~~13~~ 16. Completion of Probation

OPTIONAL CONDITIONS
17. Suspension
~~14.~~ 18. Community Services Program
~~15.~~ 19. Restitution
~~16.~~ 20. Separate File of Records
~~17.~~ 21. Report of Controlled Substances
~~18.~~ 22. Surrender of DEA Permit
~~19.~~ 23. Posted Notice of Suspension

STANDARD CONDITIONS: TO BE INCLUDED IN ALL PROBATIONS

1. Definition: Respondent

For the purposes of these terms and conditions, "respondent" shall refer to [insert name] and all terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by respondent to or before the board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

~~1~~ 2. Obey All Laws

Respondent ~~owner~~ shall obey all state and federal laws and regulations.

Respondent ~~owner~~ shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's _____ license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug~~,~~ device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

~~2~~ 3. Report to the Board

Respondent ~~owner~~ shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent ~~owner~~ shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

~~3~~ 4. Interview with the Board

Upon receipt of reasonable prior notice, respondent ~~owner~~ shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

~~4~~ 5. Cooperate with Board Staff

Respondent ~~owner~~ shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of ~~his or her~~ the probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

~~5~~ 6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent ~~owner~~ shall pay to the board its costs of investigation and prosecution in the amount of $_____. Respondent ~~owner~~ shall make said payments as follows: _____. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent ~~owner~~ shall not relieve respondent of ~~his or her~~ its responsibility to reimburse the board its costs of investigation and prosecution.

OPTION: Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

~~6~~ 7. Probation Monitoring Costs

Respondent ~~owner~~ shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

~~7~~ 8. Status of License

Respondent ~~owner~~ shall, at all times while on probation, maintain current licensure with the board. ~~If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board.~~ Failure to maintain current licensure shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

~~8~~ 9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent ~~owner~~ discontinue business, respondent ~~owner~~ may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other

action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

OPTION (To be included if the respondent is a pharmacy): Upon acceptance of the surrender, respondent ~~owner~~ shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent ~~owner~~ shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer within five (5) days.

Respondent ~~owner~~ shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent ~~owner~~ shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent ~~owner~~ may not apply for any new ~~licensure~~ license from the board for three (3) years from the effective date of the surrender. Respondent ~~owner~~ shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent ~~owner~~ further stipulates that ~~he or she~~ it shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent and the assumption of practice at that location by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number.

~~9~~ 11. Notice to Employees

Respondent ~~owner~~ shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent ~~owner~~ shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent ~~owner~~ shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

~~10~~ 12. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

Respondent shall remain open and engaged in its ordinary business as a [insert license type] in California for a minimum of _____ hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the board or its designee. If respondent is not open and engaged in its ordinary business as a [insert license type] for a minimum of _____ hours in any calendar month, for any reason (including vacation), respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open and engaged in its ordinary business as a [insert license type] in California for a minimum of _____ hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

~~11~~ 14. Posted Notice of Probation

Respondent ~~owner~~ shall prominently post a probation notice provided by the board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation. ~~The probation notice shall remain posted during the entire period of probation.~~

Respondent ~~owner~~ shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

~~Failure to post such notice shall be considered a violation of probation.~~

~~12~~ 15. Violation of Probation

If a respondent ~~owner~~ has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent ~~owner~~ violates probation in any respect, the board, after giving respondent ~~owner~~ notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. ~~Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license.~~ If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

~~13~~ 16. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

OPTIONAL CONDITIONS OF PROBATION

~~14~~ 17. Suspension

As part of probation, respondent's license to operate a [insert license type] is suspended for _____ [day(s)/month(s)/year(s)] beginning the effective date of this decision. Respondent shall cease all operations as a [insert license type] during the period of suspension. Failure to comply with any such suspension shall be considered a violation of probation.

~~14.~~ 18. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent ~~owner~~ shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services to a community or charitable facility or agency for at least _____ hours per _____ for the first _____ of probation.

Within thirty (30) days of board approval thereof, respondent ~~owner~~ shall submit documentation to the board demonstrating commencement of the community service program. Respondent ~~owner~~ shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

~~15.~~ 19. Restitution (Appropriate in cases of drug diversion, theft, fraudulent billing, or patient harm resulting from negligence or incompetence.)

Within _____ days of the effective date of this decision, respondent ~~owner~~ shall pay restitution to _____ in the amount of $ _____. Failure to make restitution by this deadline shall be considered a violation of probation.

~~16.~~ 20. Separate File of Controlled Substances Records

Respondent ~~owner~~ shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

~~17.~~ 21. Report of Controlled Substances

Respondent ~~owner~~ shall submit ~~quarterly~~ reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent ~~owner~~ shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent ~~owner~~ shall report on a quarterly basis or as directed by the board or its designee. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

~~18.~~ 22. Surrender of DEA Permit

Within thirty (30) days of the effective date of this decision, respondent ~~pharmacy~~ shall surrender its federal Drug Enforcement Administration (DEA) permit to the DEA, for cancellation. Respondent ~~pharmacy~~ shall provide documentary proof of such cancellation to the board or its designee. Thereafter, respondent ~~pharmacy~~ shall not apply/reapply for a DEA registration number without the prior written consent of the board or its designee.

Option**:** Respondent ~~pharmacy~~ may obtain a DEA permit restricted to Schedule(s) _____ controlled substance(s).

Option**:** Respondent ~~pharmacy~~ shall not order, receive, or retain any federal order forms, including DEA Form 222 ~~forms~~, for controlled substances.

~~19.~~ 23. Posted Notice of Suspension

Respondent ~~owner~~ shall prominently post a suspension notice provided by the board in a place conspicuous and readable to the public within two (2) days of receipt thereof from the board or its designee. The suspension notice shall remain posted during the entire period of suspension ordered by this decision. Failure to timely post such notice, or to maintain the posting during the entire period of suspension, shall be considered a violation of probation.

Respondent ~~owner~~ shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

~~6/2007~~ 9/2012

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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Legislation and Regulation Committee

Greg Lippe, Chair, Public Member
Ramón Castellblanch, Public Member
Randy Kajioka, Professional Member
Amy Gutierrez, Professional Member
Tappan Zee, Public Member

PART III – LEGISLATION AND REGULATION COMMITTEE

The Legislation and Regulation Committee has not met in the past quarter.

a. First Quarterly Report on the Committee's Goals for 2012/2013

The strategic goals update for the Legislation and Regulation Committee is under development by staff and will be reviewed by the committee in advance of the January 2013 Board Meeting.